

---

**AN HISTORICAL AND CONTEMPORANEOUS  
ANALYSIS OF PATENTING OF METHODS OF  
MEDICAL TREATMENT OF HUMAN BEINGS IN  
AUSTRALIA AND OVERSEAS**

---

**By**

**Oksana Mitnovetski**

**BMEng, LLB (Honours), Australian Legal Practitioner**

**Submitted in fulfilment of the requirements for the Degree of Master of Laws**

**University of Tasmania**

**Faculty of Law**

**July 2008**

### **CANDIDATE'S STATEMENT**

I declare that the work presented in this thesis contains no material which has been accepted for a degree or diploma by the University or any other institution except by way of background information and duly acknowledged in the thesis, and to the best of my knowledge and belief no material previously published or written by another person except where due acknowledgement is made in the text of the thesis.

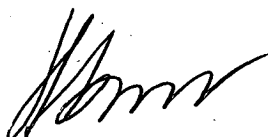


---

Oksana Mitnovetski

### **AUTHORITY OF ACCESS**

This thesis may be made available for loan and limited copying on accordance with the *Copyright Act 1968* (Cth).



---

Oksana Mitnovetski

5 December 2007

To the best of the author's knowledge this thesis states the law as at 5 December 2007.

## **ACKNOWLEDGEMENTS AND THANKS**

A special gratitude goes to my supervisor Dr Dianne Nicol for her continuous support in completing the thesis. Dianne was always there for me when I needed her advice, assistance and encouragement. I am in great debt for her time spent in marking up my chapters and providing comments on the drafts of the thesis.

Thanks to Professor Don Chalmers for reviewing the chapters and providing valuable comments and feedback. I would particularly like to thank Professor Gino Dal Pont for proofreading of my thesis and asking good questions to think about. I also thank Michael Stokes who gave insightful comments on Chapter 6. I would also like to thank the staff of the Law School Library for their ongoing support.

I could never leave out my thanks to my parents Alexei and Tamara, for giving me life in the first place, for educating me well, for their unconditional support and encouragement, even when this went beyond boundaries of language and geography. My deepest thanks also go to my beautiful sons Evgeni, Alexei and Alexander for their love, patience, support and understanding. Finally, saving the most important for last, I want to thank my husband, Sergei, for his encouragement and wisdom during the last six years. Being so strong and kind, he has provided the needed air to breath, balance, insight and direction.

## ABSTRACT

This thesis makes an historical and contemporaneous analysis of patenting of methods of medical treatment of human beings in Australia and other common law jurisdictions that derived their origin from the UK law. The issue of patenting of methods of medical treatment has never been an easy question to discuss for it raises public policy considerations surrounding this area. The main difficulty derives from the conflict between the intellectual property and practice of medicine. There is a public policy concern that in order to ensure the best possible health treatment, physicians must always be free in their choice of treatment. Since a patent may restrict this freedom, many countries around the globe prohibit methods of medical treatment from being granted patent protection. Yet, Australian courts decided to depart from those exclusions.

This thesis examines how courts deal with express exclusions of patents for method of medical treatment and how such exclusions can be avoided by creative drafting of patent specifications. It will also examine the approach taken in Australia where there are no express exclusions. It first provides the descriptive background of the case law in UK, Member States of the European Patent Convention, Canada, Israel, New Zealand, US and Australia in order to make a comparative analysis of the approaches adopted in these countries in dealing with the issue, and in order to establish the framework around which the doctrinal issues can be analysed.

Against this background an examination of the origins of the patent law is necessary in order to fully assess the interpretation of patent legislation by courts and consequences of such interpretation for medical profession. The thesis investigates the pre-enacting history of the *1624 Statute of Monopolies* in order to analyse whether patenting of methods of medical treatment of human beings is 'generally inconvenient' within the meaning of the proviso to s 6 of the *Statute of Monopolies*, which in turn, form a part of s 18 (1) of the *Patents Act 1990* (Cth).

The analysis of early patent law cases at the time they were argued and decided will lead to the conclusion that the actual original meaning of the term 'generally inconvenient' has been wrongly interpreted and applied by modern courts. The thesis considers the role of the courts in deciding whether methods of medical treatment should be granted patent protection and whether judges should and/or have ability to make moral or public policy judgments in interpreting statutes.



The thesis explore the consequences of interpretation of 'generally inconvenient' as a main public policy objection to granting patents for methods of medical treatment. It concludes that it is questionable whether the term 'generally inconvenient' includes public policy considerations in its scope, and though there may be some circumstances where a patent to method of medical treatment should be rejected on public policy grounds, 'generally inconvenient' does not provide a basis upon which patents to methods of medical treatment can be denied.

The thesis is that such methods should not be expressly excluded from patenting. Each method must be treated equally with other inventions and examined on its merits, on case by case basis. The tensions associated with patents for methods of medical treatment can be resolved within patent legislation by making the public policy ground for objection a separate criterion for patentability, equally relevant for any invention. Accordingly, the author argues that legislative amendments are necessary to rectify the existing problem and makes a number of proposals to this effect. The author also suggests the involvement of an independent body to make public policy decisions.

## TABLE OF CONTENTS

PAGE NO.

### INTRODUCTION

|  |   |
|--|---|
| The Problem with Patents for Methods of Medical Treatment..... | 1 |
| The Scope of this Thesis.....                                  | 4 |

### CHAPTER 1

#### PATENTABILITY OF METHODS OF MEDICAL TREATMENT IN THE UNITED KINGDOM PRIOR TO 1977

|         |   |    |
|---------|---|----|
| 1.1     | Introduction .....  | 7  |
| 1.2     | The Statutory Provisions Prior To 1977 .....  | 8  |
| 1.3     | The Development Of English Common Law Prior To 1977.....  | 8  |
| 1.3.1   | Methods of medical treatment and manner of manufacture in <i>C &amp; W's Application</i> .....  | 9  |
| 1.3.2   | The 'vendibel product' rule and its application in <i>Matter of an Application for a Patent by GEC (GEC's Application)</i> and beyond.....          | 10 |
| 1.3.2.1 | <i>GEC's Application</i> .....  | 10 |
| 1.3.2.2 | <i>Henry Barnato Rantzen's Application (Rantzen's Application)</i> .  | 11 |
| 1.3.2.3 | <i>Canterbury Agricultural College's Application</i> .....  | 12 |
| 1.3.3   | First doubts regarding the correctness of the 'Vendible Product' Rule in <i>Swift &amp; Co's Application</i> .....                                  | 13 |
| 1.3.4   | One stage further in the frontier of patentability: <i>United States Rubber Company's Application</i> .....   | 15 |
| 1.3.5   | Release from the restrictions of the 'vendible product' test by English courts: <i>Schering AG's Application</i> .....                              | 17 |
| 1.3.6   | Applications of the <i>Schering</i> case .....  | 20 |
| 1.3.6.1 | <i>Calmic Engineering Co Ltd's Application</i> .....  | 20 |
| 1.3.6.2 | <i>Dow Corning Corporation (Bennett's) Applications</i> .....   | 21 |
| 1.3.7   | The first applications of the proviso to s 6 of the Statute of Monopolies by the English courts: <i>Eli Lilly &amp; Company's Application</i> ..... | 22 |
| 1.4     | Conclusion.....   | 24 |

### CHAPTER 2

#### THE EUROPEAN PATENT CONVENTION AND THE EUROPEAN COUNTRIES

|     |   |    |
|-----|---|----|
| 2.1 | Introduction .....  | 26 |
| 2.2 | The United Kingdom: Banks Committee Report .....              | 28 |
| 2.3 | Development of Exclusionary Provisions in the European Patent |    |

|   |           |
|---|-----------|
| <b>Convention .....</b>   | <b>31</b> |
| <b>2.4 The Exclusionary Scope of Art 52(4) EPC .....</b>                              | <b>33</b> |
| 2.4.1 Art 52(4), first sentence: surgery, therapy and diagnosis.....                  | 35        |
| 2.4.1.1 The field of surgery .....  | 36        |
| 2.4.1.2 The field of therapy (prophylaxis and relief and pain) .....                  | 38        |
| 2.4.1.3. The field of diagnosis .....   | 41        |
| 2.4.2 Cosmetic products and therapeutic treatments .....                              | 43        |
| 2.4.3 Conclusions on the case law relating to the interpretation of<br>Art 52(4)..... | 45        |
| <b>2.5 Swiss-Type Claims Under Art 54(5) EPC.....</b>                                 | <b>46</b> |
| 2.5.1 First Therapeutic Use .....   | 47        |
| 2.5.2 Second Therapeutic Use .....  | 47        |
| 2.5.2.1 Germany. <i>Hydropyridine</i> .....   | 48        |
| 2.5.2.2 The European Patent Office: <i>Eisai</i> .....                                | 48        |
| 2.5.2.3 The United Kingdom: <i>Wyeth</i> and <i>Schering</i> .....                    | 49        |
| 2.5.2.4 Sweden and Netherlands.....   | 50        |
| 2.5.3 Criticism of Swiss-Type Claims.....   | 50        |
| <b>2.6 Inventions Contrary To 'Ordre Public' Or Morality .....</b>                    | <b>52</b> |
| <b>2.7 Conclusion .....</b>   | <b>56</b> |

## CHAPTER 3

### PATENTABILITY OF METHODS OF MEDICAL TREATMENT IN OTHER COUNTRIES OUTSIDE AUSTRALIA

|  |           |
|--|-----------|
| <b>3.1 Introduction .....</b>                                    | <b>60</b> |
| <b>3.2 Canada .....</b>  | <b>61</b> |
| 3.2.1 Relevant Statutory Provisions .....                        | 61        |
| 3.2.2 Case Law.....  | 61        |
| 3.2.2.1 <i>Tennessee Eastman Co v The Commissioner</i> .....     | 61        |
| 3.2.2.2 Decisions After the <i>Tennessee Case</i> .....          | 62        |
| 3.2.3 'Use of Claims'.....                                       | 64        |
| 3.2.4 Summary of the Canadian Position.....                      | 64        |
| <b>3.3 Israel.....</b>   | <b>65</b> |
| 3.3.1 Relevant Statutory Provisions .....                        | 65        |
| 3.3.2 Case Law.....  | 66        |
| 3.3.3 'Use of Claims'.....                                       | 68        |
| 3.3.4 Summary of the Israeli Position .....                      | 69        |
| <b>3.4 New Zealand .....</b>                                     | <b>69</b> |
| 3.4.1 Relevant Statutory Provisions .....                        | 69        |
| 3.4.2 Development of New Zealand Case Law .....                  | 70        |
| 3.4.2.1 <i>Maeder v 'Ronda' Ladies' Hairdressing Salon</i> ..... | 71        |

|            |   |           |
|------------|---|-----------|
| 3.4.2.2    | <i>Swift &amp; Co v Commissioner of Patents</i> .....   | 71        |
| 3.4.2.3    | <i>Wellcome Foundation Ltd v Commissioner of Patents</i> .....  | 72        |
| 3.4.2.4    | The Practice of the New Zealand Patent Office.....  | 76        |
| 3.4.3      | 'Use of Claims'.....  | 77        |
| 3.4.3.1    | <i>Pharmaceutical Management Agency Ltd v The<br/>Commissioner of Patents</i> .....                       | 77        |
|            | (a) The Judgement of Gallen J in the High Court.....  | 78        |
|            | (b) The Court of Appeal.....  | 79        |
| 3.4.3.2    | <i>Pfizer Inc v Commissioner of Patents</i> .....   | 82        |
| 3.4.4      | Summary of Position in New Zealand .....  | 84        |
| <b>3.5</b> | <b>The United States</b> .....  | <b>85</b> |
| 3.5.1      | Relevant Statutory Provisions .....   | 85        |
| 3.5.2      | Early Case Law and Legislation.....   | 86        |
| 3.5.2.1    | The Vulcanized Rubber Story .....   | 86        |
| 3.5.2.2    | <i>Morton v New York Eye Infirmary</i> .....  | 87        |
| 3.5.2.3    | <i>Ex Parte Brinkerhoff</i> .....   | 88        |
| 3.5.2.4    | 57 <sup>th</sup> Congress in 1902 and 58 <sup>th</sup> in 1903.....                                       | 89        |
| 3.5.2.5    | The Situation After the 1902 and 1903 Bills .....   | 90        |
| 3.5.2.6    | <i>Ex Parte Scherer</i> .....   | 90        |
| 3.5.3      | The Pallin Patent and its Consequences .....  | 93        |
| 3.5.3.1    | <i>Pallin v Singer</i> .....  | 92        |
| 3.5.3.2    | Attempts to change US law following <i>Pallin v Singer</i> .....  | 94        |
| 3.5.3.3    | Current legislation – 35 US Code § 287 (c) .....  | 95        |
| 3.5.4      | Summary of US Position.....   | 97        |
| <b>3.6</b> | <b>Conclusions – Comparative Analysis</b> .....   | <b>97</b> |
| 3.6.1      | Key Features of Canadian Law.....   | 98        |
| 3.6.2      | Key Features of Israely Law .....   | 99        |
| 3.6.3      | Key Features of New Zealand Law .....   | 99        |
| 3.6.4      | Implications of Canadian, Israely and New Zealand Laws on the<br>Medical Profession in Each Country ..... | 100       |
| 3.6.5      | The United States .....   | 102       |
| 3.6.5.1    | Key Features of US Law.....   | 102       |
| 3.6.5.2    | Implications of US patent law on the US medical<br>profession.....  | 103       |

## CHAPTER 4

### PATENTING OF METHODS OF MEDICAL TREATMENT IN AUSTRALIA

|            |  |            |
|------------|--|------------|
| <b>4.1</b> | <b>Introduction</b> .....                  | <b>106</b> |
| <b>4.2</b> | <b>Relevant Statutory Provisions</b> ..... | <b>107</b> |

|            |   |            |
|------------|---|------------|
| <b>4.3</b> | <b>The Requirements for a Valid Patent.....</b>   | <b>108</b> |
| 4.3.1      | Requirements of s18(1) .....  | 108        |
| 4.3.2      | Novelty and Inventive Step Requirements .....   | 109        |
| 4.3.3      | 'Patentable Invention' Within the Meaning of Opening Words of<br>Ss18(1) and 18(1)(a).....                                  | 110        |
| 4.3.3.1    | The opening words of s18(1): 'a patentable invention<br>is an invention that...' .....                                      | 110        |
| 4.3.3.2    | Section 18(1)(a): 'a manner of manufacture...' .....  | 113        |
| <b>4.4</b> | <b>The 'Pure' Manner of Manufacture Test .....</b>  | <b>114</b> |
| 4.4.1      | Historical Development of the <i>Manner of Manufacture</i> Concept.....   | 114        |
| 4.4.2      | <i>National Research Development Corporation v Commissioner<br/>of Patents</i> .....  | 116        |
| 4.4.2.1    | The threshold requirement of inventiveness.....   | 116        |
| 4.4.2.2    | Whether the process has fallen within the category of<br>'invention' under the 1952 Act .....                               | 117        |
| <b>4.5</b> | <b>Patenting of Methods of Medical Treatment .....</b>  | <b>119</b> |
| 4.5.1      | Issue 1: are methods of medical treatment a 'manner of<br>manufacture' within s6 of the <i>Statute of Monopolies</i> ?..... | 119        |
| 4.5.1.1    | <i>Maeder v Busch</i> .....   | 119        |
| 4.5.1.2    | <i>National Research Development Corporation v Commissioner<br/>of Patents</i> .....  | 120        |
| 4.5.1.3    | <i>Joos v Commissioner of Patents</i> .....   | 121        |
| 4.5.1.4    | Conclusion regarding Issue 1.....   | 124        |
| 4.5.2      | Issue 2: do methods of medical treatment fall within the proviso to<br>s 6 so as to be excluded from patentability?.....    | 124        |
| 4.5.2.1    | <i>Anaesthetic Supplies Pty Ltd v Rescare Ltd</i> .....   | 125        |
| (a)        | The judgement of Gummow J of the Federal<br>Court of Australia.....   | 126        |
| (b)        | The majority decision of the Full Court of the Federal<br>Court .....   | 127        |
| (c)        | The dissenting judgement of Sheppard J.....   | 129        |
| (d)        | The main points about <i>Rescare</i> case.....  | 130        |
| 4.5.2.2    | <i>Bristol-Myers Squibb Co v FH Faulding &amp; Co Ltd</i> .....   | 131        |
| (a)        | The Judgement of Heerey J.....  | 132        |
| (b)        | The Decision of the Full Federal Court.....   | 133        |
|            | • The judgement of Black CJ and Lehane J .....  | 134        |
|            | • The judgement of Finkelstein J.....   | 135        |
| 4.5.3      | The Effect of the Decisions in <i>Rescare</i> and <i>BMS</i> on the Australian<br>Medical Profession .....                  | 138        |
| <b>4.6</b> | <b>Conclusion .....</b>   | <b>140</b> |

## CHAPTER 5

### THE PROVISO TO SECTION 6

|            |  |            |
|------------|--|------------|
| <b>5.1</b> | <b>Introduction .....</b>  | <b>142</b> |
| <b>5.2</b> | <b>History of the Proviso to s 6 of the <i>Statute of Monopolies</i> .....</b>                                   | <b>144</b> |
| 5.2.1      | Pre-Enacting History .....   | 144        |
| 5.2.1.1    | Letters Patent .....   | 144        |
| 5.2.1.2    | Early English industrial grants and meaning of 'invention' ....  | 145        |
| 5.2.1.3    | Clauses to secure the fulfillment of the promise by<br>the grantee .....   | 145        |
|            | (a) Limitation of time clause .....  | 146        |
|            | (b) The apprenticeship clause .....  | 147        |
|            | (c) The 'inconveniency' proviso (1575) .....   | 147        |
| 5.2.1.4    | Conclusion regarding 'limitation of time' and<br>'apprenticeship' clauses .....                                  | 148        |
| 5.2.2      | Particular forms of 'inconveniency' – the invention must be new and<br>useful .....                              | 149        |
| 5.2.2.1    | <i>Matthey's case</i> (1571) and <i>Bircot's case</i> (1572) .....   | 149        |
| 5.2.2.2    | Conclusion regarding <i>Matthey's</i> and <i>Bircot's</i> cases .....  | 150        |
| 5.2.3      | Abuse of monopoly system .....   | 152        |
| 5.2.4      | <i>Darcy v Allen (The Case of Monopolies)</i> (1602) .....   | 152        |
| 5.2.4.1    | An infringement action against Thomas Allen .....  | 153        |
| 5.2.4.2    | Argument for the plaintiff, Edward Darcy – a novel<br>theory on which to base exception .....                    | 153        |
| 5.2.4.3    | Argument for the defendant, Thomas Allen .....   | 155        |
|            | (a) Arguments of Fuller regarding restraint of trade .....   | 156        |
|            | (b) Arguments of Fuller and Diott regarding patents of<br>innovation: 'inconvenient' meant 'no innovation' ..... | 157        |
| 5.2.4.4    | Conclusion regarding <i>The Case of Monopolies</i> .....   | 158        |
| 5.2.4      | The Book of Bounty (1610) – the King's ninth proviso .....   | 159        |
| <b>5.3</b> | <b>The Enactment of the Statute Of Monopolies (1621-1624) .....</b>  | <b>160</b> |
| 5.3.1      | Debating the Bill .....  | 160        |
| 5.3.2      | 19 April 1624 conference in the House of Commons – the provisos<br>to the Monopolies Bill .....                  | 160        |
| 5.3.2.1    | New inventions are not void – further light on the meaning<br>of 'inconvenient' .....                            | 161        |
| 5.3.3      | No distinction between 'contrary to law' and 'inconvenient' .....  | 161        |
| 5.3.4      | The royal assent .....   | 162        |
| <b>5.4</b> | <b>Post - 1624 History of the Proviso .....</b>  | <b>163</b> |
| <b>5.5</b> | <b>Applications of the Rules of Statutory Interpretation .....</b>   | <b>164</b> |
| 5.5.1      | The literal approach and the phrase 'such manufactures<br>[shall] be not... generally inconvenient' .....        | 165        |
| 5.5.2      | The purposive/ legislative intent approach and the phrase 'such  |            |

|            |  |            |
|------------|--|------------|
|            | manufactures [shall] be not... generally inconvenient' .....   | 166        |
| 5.5.3      | The general rule of interpretation of provisos .....   | 167        |
| 5.5.4      | The modern usage of the phrase 'such manufactures<br>[shall] be not... generally inconvenient' ..... | 169        |
| <b>5.6</b> | <b>Conclusion .....</b>  | <b>171</b> |
| 5.6.1      | The <i>Statute of Monopolies</i> captured limitations already assigned<br>by the common law .....    | 171        |
| 5.6.2      | Sources for the term 'inconvenient'/'inconveniency' .....  | 171        |
| 5.6.3      | Is the term 'a catch-all justification' or a specific saving clause? .....                           | 172        |
| 5.6.4      | How should the term be interpreted? .....  | 173        |

## CHAPTER 6

### CONCLUSIONS AND PROPOSALS

|            |   |            |
|------------|---|------------|
| <b>6.1</b> | <b>Introduction .....</b>                                   | <b>175</b> |
| <b>6.2</b> | <b>The Exclusion in Practice – Chapters 1- 3 .....</b>      | <b>175</b> |
| <b>6.3</b> | <b>The Australian Position – Chapter 4.....</b>             | <b>181</b> |
| <b>6.4</b> | <b>The Proviso to Section 6: Its Original Meaning .....</b> | <b>183</b> |
| 6.4.1      | Where does the term 'generally inconvenient' fit in? .....  | 184        |
| <b>6.5</b> | <b>What Next?.....</b>                                      | <b>185</b> |
| <b>6.6</b> | <b>Deficiencies in Reviewed Approaches .....</b>            | <b>185</b> |
| <b>6.7</b> | <b>Proposals .....</b>                                      | <b>186</b> |
| 6.7.1      | Option One .....  | 186        |
| 6.7.2      | Option Two .....  | 187        |
| 6.7.3      | Option Three .....  | 187        |
| 6.7.4      | Option Four .....   | 189        |
| 6.7.5      | Option Five .....   | 191        |

|                          |            |
|--------------------------|------------|
| <b>BIBLIOGRAPHY.....</b> | <b>192</b> |
|--------------------------|------------|

## TABLE OF CASES

### AUSTRALIA

- Advanced Building System Pty & Anor v Ramset Fasteners (Aust) Pty Ltd* (1998) 194 CLR 171
- A-G for the State of Victoria ex rel Black v Commonwealth* (1981) 146 CLR 559
- Anaesthetic Supplies Pty Ltd v Rescare Ltd* (1992) 25 IPR 119
- Anaesthetic Supplies Pty Ltd v Rescare Ltd* (1994) 50 FCR 1
- Bristol-Myers Squibb Co v F H Faulding & Co Ltd* [1998] 860 FCA 22
- Bristol-Myers Squibb Co v F H Faulding & Co Ltd* [2000] FCA 316
- CCOM Pty Ltd v Jiejing Pty Ltd* (1994) 28 IPR 481
- Commissioner of Patents v Microcell* (1959) 102 CLR 232
- Cooper Brookes (Wollongong) Pty Ltd v Commissioner of Taxation (Cth)* (1981) 147 CLR 297
- Crnisanin v Logan* (1972) 4 SASR 340
- Dorman v Rodgers* (1982) 148 CLR 365
- IBM Corporation v Smith, Commissioner of Patents* (1991) 22 IPR 417
- Geelong Harbor Trust Commissioner v Gibbs Bright* (1974) 129 CLR 576
- H Buckman and Son Pty Ltd v Flanagan* (1974) 133 CLR 422
- Maeder v Busch* (1938) 59 CLR 684
- McGinty v Western Australia* (1996) 186 CLR 140
- McGuire v Simpson* (1977) 139 CLR 362
- McMahon v Northern territory Insurance Office* (1984) 26 NTR 5
- Joos v Commissioner of Patents* (1972) 126 CLR 611
- National Research Development Corporation v Commissioner of Patents* (1959) 102 CLR 252
- NV Philips Gloeilampenfabrieken and Another v Mirabella International Pty Ltd* (1995) 183 CLR 655
- Tasmania v Commonwealth* (1904) 1 CLR 329
- Welcome Real-Time SA v Catuity Inc* [2001] FCA 445

### CANADA

- ICI v The Commissioner* (1986) 9 CPR (3d) 289
- Merck & Co v Apotex* (1995) 59 CPR (3d) 133



*Re Application of Ackerman* (1977) 105 CPOR 14-xviii

*Re Application For Patent of Goldenberg* (1988) 22 CPR 159

*Tennessee Eastman Co v The Commissioner* (1972) 8 CPR (2d) 202

*Visx v Nidek* (1996) 66 CPR (3d)

## **EUROPEAN PATENT CONVENTION**

*Eisai/Second Medical Indication* (1985) OJ EPO 60

*Harvard/Oncomouse* [1990] EPOR 501

*Hydropyridine* (1984) OJ EPO 26

*Hydropyridine/SE* (1988) OJ EPO 198

*Implantieren v Haarbundeln* (1988) 30 Bpat GE 134

G 5/83, 1985 OJ EPO 64

*Octooiraad* (1988) OJ EPO 405

T 144/83, *Appetite Suppressant/Du Pont* (1986) OJ EPO 301

T 964/99, *Cycnus Inc* (2002) OJ EPO 1

T 81/84, *Dysmenorrhea/Rorer* (1988) OJ EPO 207

T 385/86, *Non-Invasive Measurement/Bruker* (1988) OJ EPO 308

T 35/99, *Pericardial Access/Georgetown* (2000) OJ EPO

T 116/85, *Pigs I/Wellcome* (1989) OJ EPO 13

T 19/86, *Pigs II/ Duphar* (1989) OJ EPO 24

T 36/83, *Thenoyl Peroxide/Roussel-Uclaf* (1986) OJ EPO 295

T 290/86, 1992 OJ EPO 414

T 182/90, 1994 OJ EPO

T 820/92, 1995 OJ EPO

T 83/93, 1996 OJ EPO

T 82/93, 1996 OJ EPO

T 655/92, 1998 OJ EPO 17

T 329/94, 1998 OJ EPO 242

## **GERMANY**

*Benzene sulfonyl urea* 9 IIC 42 (1978)

*Glatzenoperation* 48 BGHZ 313, 1968 GRUR 142

*Sitosterylglycosides* 14 IIC 283 (1983)

## **ISRAEL**

*Wellcome Foundation Ltd v Plantex Ltd and Another* [1974] RPC 514

## **NEW ZEALAND**

*Commissioner of Patents v Wellcome Foundation Ltd* [1983] 1 IPR 156

*Maeder v "Ronda" Ladies' Hairdressing Salon* [1943] NZLR 122

*Re Securitibank Ltd (in liquidation)* [1978] 1 NZLR 97

*Pharmaceutical Management Agency Limited v The Commissioner of Patents & Ors* [1999] NZCA 332

*Pfizer Inc v Commissioner of Patents* [2004] NZCA 104

*Swift & Co v Commissioner of Patents* [1960] NZLR 775

*The Wellcome Foundation Ltd v Plantex Ltd (also known as Wellcome Foundation's (Hitchings') Application (New Zealand))* [1979] 2 NZLR 591

## **SWEDEN**

*Patentbesvarsratten*

## **UNITED KINGDOM**

*A-G's Reference (No 1 of 1981)* [1982] QB 848

*Barnato Rantzen's Application* (1947) 64 RPC 63

*Bocconi's Application* (1967) AOJP 1380.

*Boulton v Bull* (1795) 126 ER 651

*Bristol-Myers Squibb Co v Baker Norton Pharmaceuticals Inc* [1999] RPC 253

*British Petroleum Co Ltd's Application* (1968) 38 AOJP 1020

*Calmic Engineering Co Ltd's Application* [1973] RPC 684

*Campbell College Belfast (Governors) v Commissioners of Valuation for Northern Ireland* [1964] 1 WLR 912

*Canterbury Agricultural College's Application* (1958) 75 RPC 85

*Cartledge v E Jopling and Sons Ltd* [1963] AC 758

*Clayton Furniture Ltd's Application* (1965) AOJP 2303

*Crane v Price* (1842) 134 ER 239

*Darcy v Allen* (1602) Moore KB 671, (1603) Noy 173-185, 74 Eng Rep 1131, 11 Co Rep 84b-88b, 77 Eng Rep 1260

*Donoghue v Stevenson* [1932] AC 562

*Dow Corning Corporation (Bennett's) Applications* [1974] RPC 235

*Duport Steels Ltd v Sirs* [1980] 1 ALL ER 529

*Eli Lilly & Company's Application* [1975] RPC 438

*Hawkins v Gathercole* (1855) 6 D GM & G 1

*Heydon Case* (1584) 3 Co Rep 7a

*Hilder v Dexter* [1902] AC 474

*Imperial Tobacco Ltd v Attorney-General* [1979] QB 555

*In the Matter of an Application for a Patent by GEC* (1942) 60 RPC 1

*In the Matter of C & W's Application for a Patent* (1914) 31 RPC 235

*John Wyeth & Brother Ltd's Application and Schering AG's Application* [1985] RPC 545

*Kirkness (Inspector of Taxes) v Hudson* [1955] AC 696

*R v City of London Court Judge* [1892] 1 QB 273

*R v Wimbledon JJ ex p Derwent* [1953] 1 QB 380

*R v Wheeler* (1819) 106 ER 392

*Re BA's Application* (1915) 32 RPC 348

*Re Compagnies Reunies des Glaces et Verres Speciaux du Nord de la France* (1930) 48 RPC 185

*Re L & G's Patent* (1940) 58 RPC 21

*Re Rowland* [1963] 1 Ch 1 (CA)

*Re Schering AG's Application* [1971] RPC 337

*River Wear Commissioners v Adamson* (1877) 2 App Cas 743

*Rolls-Royce Ltd's Application* [1963] RPC 251

*Samuel Reitzman v Grahame-Chapman and Derustit Ltd* (1950) 68 RPC 25

*Schering AG's Application* [1971] 3 All ER 177

*Sharp and Dohme Inc v Boots Pure Drug Company Ltd* (1928) 45 RPC 153

*Sharp v Wakefield* (1888) 22 QBD 239

*Swift & Co's Application* [1961] RPC 129

*Telefon A/B LM Ericssons Application* (1974) 44 AOJP 846

*The Wellcome Foundation Ltd v Plantex Ltd and other* [1974] RPC 514

*Unilever Ltd (Davis's) Application* 1983 RPC 219

*United States Rubber Company's Application* [1964] RPC 104

*Upjohn Company (Robert's) Application* [1977] RPC 94

*V S Clark's Application* (1969) AOJP 1638

## **UNITED STATES**

*Diamond v Chakrabarty* (1980) 447 US 303

*Ex Parte Brinkerhoff* (1892) 146 US 515

*Ex Parte Scherer* (1954) 103 USPQ 107

*Kewanee Oil Co v Bicron* (1974) 416 US 470

*Martin v Wyeth* (1951) 96 F Supp 689

*Morton v New York Eye Infirmary* 17 F Cas 879 (CCSDNY 1862)

*Pallin v Singer* (1995) 36 USPQ 2d (BNA) 1050

*Seymour v Osborn* (1970) 78 US 516

## **OTHER**

Canadian Patent Office, *Manual of Patent Office Practice* (1998), Government of Canada, Ottawa, see <http://patents1.ic.gc.ca/> (date accessed: 5 June 2007)

## TABLE OF STATUTES

### AUSTRALIA

*Acts Interpretation Act 1901 (Cth)*

*Judiciary Act 1903 (Cth)*

*Patents Act 1903 (Cth)*

*Patents Act 1952 (Cth)*

*Patents Act 1990 (Cth)*

### CANADA

*Patent Act RSC 1952*

*Patents Act RSC 1985*

### ISRAEL

*Mandatory Patents and Designs Ordinance 1924*

*Patents Act 1967*

### NEW ZEALAND

*Patents Act 1953 (NZ)*

### UNITED KINGDOM

*Patents, Designs, and Trade Marks Act 1883 (UK)*

*Patents Act 1901 (UK)*

*Patents and Designs Act 1907 (UK)*

*Patents Act 1949 (UK)*

*Patents Act 1977 (UK)*

*Patents, Designs and Trade Marks Act 1883 (UK)*

*Patents and Designs Act 1907 (UK)*

*Patents and Designs Act 1949 (UK)*

*Statute of Monopolies 1624 (21 James I. cap. 3, 'An Act concerning Monopolies and Dispensations with the penal Lawes and the Foreytire thereof')*

### UNITED STATES

*Pubic Law No 104-208 35 USC*

*The Medical Procedures and Affordability Act*, House Bill 1127, HR 1127, 104<sup>th</sup> Cong (1995)

*The Medical Procedures and Affordability Act*, House Bill 3814, HR 3814, 104<sup>th</sup> Cong. (1996)

*The Medical Procedures and Affordability Act*, Senate Bill 2105, S 2105, 104<sup>th</sup> Cong. (1996)

*The Medical Procedures and Affordability Act*, House Bill 4278 HR 4278, 104<sup>th</sup> Cong. (1996)

US Constitution, Article I, Para 8

## **OTHER**

*Banks Committee Report on the British Patent System* (1970) Cmnd 4407

*European Patent Office Guidelines for Examination*, C-IV

*Industrial Property Advisory Committee Report on the Patents, Innovations and Competition in Australia* (1984)

New Zealand Ministry of Economic Development, *A Review of the Patents Act 1953: Boundaries to Patentability: A Discussion Paper* (2002), New Zealand, see [www.med.govt.nz/buslt/int\\_prop/patentsreview/index.html](http://www.med.govt.nz/buslt/int_prop/patentsreview/index.html) (date accessed: 15 October 2007)

## **TABLE OF TREATIES, CONVENTIONS AND AGREEMENTS**

### **AGREEMENTS**

*Agreement on Trade-Related Aspects of Intellectual Property Rights Including Trade in Counterfeit Goods* (1994) 25 IIC 209

*North American Free Trade Agreement*, [1992] 32 ILM 605 (entered into force 17 December 1992)

*Australian-US Free Trade Agreement*, [2005] ATS 1

### **TREATIES**

*Patent Cooperation Treaty* [1980] ATS 6 (entered into force 24 January 1978)

*Patent Law Treaty* 2000 WIPO (entered into force 28 April 2005)

*Treaty Establishing the European Community* [2002] OJ C 325/65

### **CONVENTIONS**

*Convention on the Grant of European Patents (European Patent Convention)* 5 October 1973, 1065 U.N.T.S. 199, E.T.S. No 16, Cmnd

*Paris Convention for the Protection of Industrial Property* [1972] ATS 12

## INTRODUCTION

### 1. The Problem with Patents for Methods of Medical Treatment

There has been ongoing and longstanding debate about whether methods of medical treatment of the human body should be patentable for almost a century. The issue is complicated as it involves two conflicting concepts - intellectual property and practice of medicine. Creations of the intellect may be given recognition by means of intellectual property rights, including patents. A patent is a temporary monopoly granted to the creator in return for disclosure of the invention to the public. Patents for industrial and consumer innovation are common and generally welcomed in our society.<sup>1</sup> The patent system is justified on the basis that it provides benefit to the inventor and to society as a whole. The inventor of a patentable invention benefits by being able to exclude others from exploiting the invention for 20 years,<sup>2</sup> and the public benefits because when the patent expires, the invention is freely available for others to use. The practice of medicine, which is based on the Hippocratic Oath, however, aims to preserve human life, disseminate medical knowledge, and deny exploitation of this knowledge for the sole benefit of a medical practitioner.

If a medical practitioner is the creator of the intellectual property that relates to medical treatment, can he/she seek a monopoly over the creation of his intellect? Will the legal rights associated with the monopoly interfere with the practitioner's moral, ethical and professional obligations of providing the best possible health treatment and dissemination of medical knowledge and information? These and many other ethical and public policy arguments have been raised against patenting of methods of medical treatment. The main argument is clear: there is a public policy concern that in order to ensure the best possible health treatment, doctors must always be free in their choice of treatment. Since patents may restrict this freedom, it has been argued that methods of medical treatment should be excluded from patent protection.

*The Agreement on Trade-related Aspects of Intellectual Property Rights 1995*<sup>3</sup> mandates the minimum standards of intellectual property protection for all

---

<sup>1</sup> However, it is recognised that patenting of some subject matters is highly controversial in contemporary society, particularly genes, higher organisms, software and business methods.

<sup>2</sup> See Art 27 and 33 *Agreement on Trade-Related Aspects of Intellectual Property Rights Including Trade in Counterfeit Goods* (1994) 25 IIC 209 (TRIPS); *Patents Act 1977* (UK), s25; *Patents Act 1990* (Cth), Ss 65 and 67.

<sup>3</sup> *Agreement on Trade-Related Aspects of Intellectual Property Rights Including Trade in Counterfeit Goods* (1994) 25 IIC 209 (TRIPS).

countries that are members of the World Trade Organisation. However, by virtue of Article 27.2 of this Agreement, member countries are allowed decide for themselves whether or not to exclude methods of medical treatment from patenting. By the year 2007, approximately 80 countries around the globe had made the decision to prohibit methods of medical treatment from being granted patent protection.<sup>4</sup> Different countries have taken different approaches in the way that they deal with this issue. In the UK, other European countries, for example, methods of medical treatment are expressly excluded from patenting.<sup>5</sup> In Canada and New Zealand, on the other hand, such methods are prohibited by common law.<sup>6</sup> In marked contrast with these approaches, in the US methods of medical treatment have been considered patentable since 1954.<sup>7</sup> However, by virtue of Public Law 104-208<sup>8</sup> patents on medical and surgical procedures are unenforceable against medical practitioners and related health care entities, unless they fall under one of three exceptions provided by the new law.<sup>9</sup>

Notwithstanding the prohibition of methods of medical treatment in many countries, such prohibition can be worked around by skilled patent attorneys in drafting a patent application in the form of the Swiss type claims..<sup>10</sup> Since Swiss type claims are directed to treatment of a particular disease, the claims provide indirect protection of therapeutic methods of medical treatment. Thus, despite the express prohibition in European patent law, only methods of treating human illness by surgery and/or diagnostic methods are excluded. This practice therefore narrows the scope of prohibition to a minimum, and in cases where therapeutic methods are involved, makes it meaningless.

The US approach under the Public Law 104-208 is also problematic. While it allows patents to methods of medical treatment, at the same time, it takes away their value by making them unenforceable against medical practitioners and related health care entities.

---

<sup>4</sup> The list includes all European countries and countries in Asia, Africa, North America, South America, Central America.

<sup>5</sup> Section 4(2) of the *Patents Act 1977* (UK) and Art 52(4) of the EPC.

<sup>6</sup> See, eg, *Pharmaceutical Management Agency Ltd v Commissioner of Patents* [1999] NZCA 332; *Pfizer Inc v Commissioner of Patents* [2004] NZCA 104; *Tennessee Eastman Co v The Commissioner* (1972) 33 DLR (3d) 459; *ICI v The Commissioner* (1986) 9 CPR (3d) 289; *Visx v Nidek* (1996) 66 CPR (3d) 178 (FCTD).

<sup>7</sup> In 1954 the Case *Ex parte Scerer* 103 USPQ (BNA) 107, overruled *Ex parte Brinkerhoff* 24 Off.Gaz.Pat 349 (Comm'r Pat. Off.1883).

<sup>8</sup> Amendment to 35 US Code § 287(c), known as Pubic Law 104-208.

<sup>9</sup> These exceptions are listed by § 616(c)(2)(A)(i-iii) of the 35 US Code.

<sup>10</sup> Swiss-type claims are named after the practice adopted by the Swiss Office of Intellectual Property, which allows patents for the use of compounds for therapeutic treatment when worded as follows: 'Use of compound X in the manufacture of a medicament for a new therapeutic use'



In Australia, methods of medical treatment are not expressly excluded from patenting by the *Patents Act 1990* (Cth) (the **1990 Act**). However, it has been argued that if such an exclusion were to be accepted by the Australian courts, it would be based upon the public policy justification that manufactures should not be 'generally inconvenient', located in the proviso to s 6 of the *1624 Statute of Monopolies* (the **Statute of Monopolies**), which in turn, forms a part of s 18 (1) of the 1990 Act.<sup>11</sup> However, the definition of 'patentable invention' in s 18 (1) provides no guidance on the meaning of the term 'generally inconvenient'. Accordingly, the issue of interpretation of the term and the question as to whether patenting of methods of medical treatment is 'generally inconvenient' has been left to the courts to determine.

Following on from the judicial interpretation of the meaning 'manner of manufacture' by the High Court of Australia in the foundational case of *National Research Development Corporation v Commissioner of Patents*,<sup>12</sup> methods of medical treatment are now considered to be a 'manner of manufacture' within s 6 of the *Statute of Monopolies*.<sup>13</sup> Yet, it is still arguable that such methods could be excluded, in reliance on the 'generally inconvenient' exclusion in the proviso to s 6 of the *Statute of Monopolies* or by other means. Following *Anaesthetic Supplies Pty Ltd v Rescare Ltd*<sup>14</sup> (**Rescare**) and *Bristol-Myers Squibb Co v F H Faulding & Co Ltd*<sup>15</sup> (**BMS**) methods of medical treatment have been granted patent protection in Australia. However, the courts in both cases accepted that the general inconvenience proviso could be used to introduce public policy considerations in patent examinations in Australia. As a result, the true ambit of general inconvenience remains uncertain<sup>16</sup> and it is likely that attempts will be made to use general inconvenience as the vehicle for introduction of public policy considerations in the future, either in respect of methods of medical treatment or in relation to other controversial subject matter.

---

<sup>11</sup> See, eg, *Anaesthetic Supplies Pty Ltd v Rescare Ltd* (1994) 50 FCR 41 (Sheppard J); *Bristol-Myers Squibb Co v F H Faulding & Co Ltd* [2000] FCA 316 (Heerey J); W. Yang 'Patent Policy and Medical Procedure Patents: The Case for Statutory Exclusion From Patentability' (1995) 1 *Boston University Journal of Science and Technology Law* 5; P. Loughlan 'Of Patents and Patients: New Monopolies in Medical Methods' (1995) 5 *Australian Intellectual Property Journal* 13.

<sup>12</sup> [1959] 102 CLR 252, 271.

<sup>13</sup> *Joos v Commissioner of Patents* (1972) 126 CLR 611.

<sup>14</sup> (1994) 50 FCR 1.

<sup>15</sup> [2000] FCA 316.

<sup>16</sup> This is because there is no clear High Court authority on the question of whether methods of medical treatment patenting is 'generally inconvenient'.

This brief overview illustrates that the issue of patenting of methods of medical treatment of human beings is complicated and depends very much on the country, its legislation, the case law and numerous public policy considerations surrounding the patentability of such methods. It is also complicated by the way the courts deal with this matter. In deciding whether methods of medical treatment of human beings should be granted patent protection, the courts seek guidance from other jurisdictions worldwide.

## 2. The Scope of this Thesis

This thesis aims to explore more broadly the appropriateness of the current law relating to patenting of methods of medical treatment in Australia. To make sense of the current Australian position, this analysis cannot be undertaken in isolation: the historical context of the Australian legislation and case law must be examined and a comparative analysis of countries with historical origins in common with Australia must also be undertaken.

The thesis will analyse the legislation and case law in various jurisdictions, and the law in Australia regarding patenting of methods of treating human illness by surgery, therapy and/or diagnostic methods, drug treatments, as well as processes for improving strength and elasticity of human nails and hair. Patenting of pharmaceutical substances or surgical equipment that may be used in a method of treatment is beyond the scope of this thesis. Neither it is intended to provide a full account of specific public policy arguments for and against the patenting of methods of medical treatment.<sup>17</sup> Rather, the aim of this thesis is to achieve two things. First, this thesis will examine the approaches adopted by the various jurisdictions, deficiencies (if any) with their approaches, and, where applicable, their mechanisms for exclusion of methods of medical treatment inventions from patenting. This examination will demonstrate that notwithstanding the express exclusion of therapeutic, surgical and diagnostic methods of medical treatment from patenting in many countries, the exclusion, in practice, is narrowed down to surgical and some diagnostic methods<sup>18</sup> because courts and

---

<sup>17</sup> For a general account of the arguments see, eg, Justine Pila, 'Methods of Medical Treatment Within Australian and United Kingdom Patents Law' (2001) *University of New South Wales Law Journal* 30; Joel J Garris, 'The Case for Patenting Medical Procedures' (1996) *American Journal of Law and Medicine* 85, 90-100; Beata Gocyk-Farber, 'Patenting Medical Procedures: A Search for a Compromise Between Ethics and Economics' (1997) *Cardozo Law Review* 1527.

<sup>18</sup> It could be argued that in relation to therapeutic medical treatments the exclusion is meaningless in the same way as the exclusion of computer programmes. See, eg *Rolls-Royce Ltd's Application* [1963] RPC 251; *British Petroleum Co Ltd's Application* (1968) 38 AOJP 1020; but since that time attitudes towards patenting of computer programs have changed: see, eg *IBM Corporation v Smith, Commissioner of Patents* (1991) 22 IPR 417 and *CCOM Pty Ltd v Jiejing Pty Ltd* (1994) 28 IPR 481.

legal practitioners have created an indirect way to obtain patent protection for methods of therapeutic and drug treatments. Hence, even though such methods are explicitly excluded, the exclusion is very easy to avoid through the wording of the patent claims and/or patent specifications.

Secondly, this thesis will analyse the fundamental historical principles of the patent law, and the origin of modern patent to assist in understanding the purpose of the *Statute of Monopolies* itself and its proviso, and actual original meaning of the term 'generally inconvenient'. The aim is to reconstruct the legal questions raised by early patent law cases at the time they were argued and decided and demonstrate that the original meaning of the term 'generally inconvenient' has been wrongly interpreted and applied by modern courts. This thesis does not question the correctness of the decisions in *Rescare* or *BMS*, but questions the reasoning behind the application of general inconvenience. This, in turn will assist in answering the question of whether or not patenting of methods of medical treatment of the human body should be denied patent protection based on interpretation of the term 'generally inconvenient' that forms part of s 18(1) of the 1990 Act.

The thesis will argue that the term 'generally inconvenient' does not permit introduction of public policy considerations in Australian patent law, thus the interpretation of the term adopted by the courts does not have a sound historical basis. This, however, does not mean that public policy should never be considered in deciding patentability. The thesis will argue that public policy considerations should only be made where the legislature specifically directs them to be made and that should be done by bodies other than judiciary. The thesis will end with proposals, the aim of which is to provide practical tools to assist the courts, Australian Patent Office or other relevant body in assessing inventions relating to methods of medical treatment of human beings.

The thesis will explore these issues in six chapters by making comparative analysis of the common and statutory law of the reviewed countries; inquiring into the history and concept of patent law and the rules of statutory interpretation in order to construct the framework upon which a comprehensive conclusion is made. The thesis can be divided into four main themes:

1. Analysis of the key aspects of patent law in respect of patenting of methods of medical treatment in UK, Member States of the European Patent Convention, Canada, Israel, New Zealand and US (Chapters 1-3).
2. Analysis of Australian approach to such patenting (Chapter 4);
3. Enquiry into the meaning of the term 'generally inconvenient' in s 6 of the *Statute of Monopolies* by making a historical review and analysis of the origin, purpose and scope of the term, and analysis of the modern interpretation of the proviso to s 6 using the general principles of statutory interpretation (Chapter 5); and
4. Proposals (Chapter 6).

## CHAPTER 1: PATENTABILITY OF METHODS OF MEDICAL TREATMENT IN THE UNITED KINGDOM PRIOR TO 1977

### 1.1 INTRODUCTION

Any discussion of patent law in common law countries must invariably start with analysis of UK law, since this is its origin, particularly the *Statute of Monopolies* 1624<sup>1</sup> (the ***Statute of Monopolies***).

Following federation in 1900, Australia adopted the *Patents and Designs Act 1907* (UK) as its own *Patents Act 1907* (Cth). Although there have been two new Acts in Australia since that time, the basic principles remain unchanged. For example, the *Statute of Monopolies* continues to be referred to in the current Australia legislation, the *Patents Act 1990* (Cth). In addition, until the mid 1980s in Australia, the English Privy Council was the highest Court of Appeal. For both of these reasons, the UK has been highly influential in the development of Australian patent law. However, the influence of UK law has been steadily diminishing since the late twentieth century. There are two main reasons for this. First, by virtue of the *Australia Act 1986* (Cth) the avenue of appeal to the Privy Council was removed. As a consequence, the Australian High Court has been developing its own distinct jurisprudence and the use of English precedents in Australia has become less persuasive. Moreover, patent law in the UK was significantly reformed in 1977 to align it more closely with the European Patent Convention and the patent legislation of other member states.

The task in this Chapter is to analyse the development in UK law up to the enactment of the *Patents Act 1977* (UK) (the **1977 Act**), to set the scene for consideration of the law in other jurisdictions in Chapters 2-3 and Australian law in Chapter 4.

Prior to the 1977 Act there was no statutory prohibition on patenting of methods of medical treatment in the UK. The prohibition arose from the cases considered either under the *Patents Act 1949* (the **1949 Act**) or earlier legislation.

An examination of the case law regarding patenting of medical treatment in the UK indicates that such methods were excluded from patentability by the courts since 1914. The exclusion was based solely on the Patent Office practice that existed prior to the well-known decision by the Solicitor-General *In the Matter of C & W's*

---

<sup>1</sup> 21 Jac. I, c.3, § 6.

*Application for a Patent*<sup>2</sup> (**C & W's Application**). In that case the practice was reaffirmed and the basis for the practice clearly set out.<sup>3</sup>

Before considering this and other cases in detail, it is necessary to be familiar with the wording of the legislation relating to the patent law.

## **1.2 THE STATUTORY PROVISIONS PRIOR TO 1977**

The relevant provisions in relation to patentable subject-matter derive from the *Patents, Designs and Trade Marks Act 1883*, s 46; *Patents Act 1907*, s 93; and the 1949 Act, s 101. These Acts defined the word 'invention', not by direct explication and in the language of its own day, but by reference to the established ambit of s 6 of the *Statute of Monopolies*.<sup>4</sup> None of these Acts included a specific exclusion for methods of human treatment. It is noteworthy that many countries, including Australia, New Zealand and Israel, have patent law provisions that are similarly derived from, or incorporate by reference s 6 of the *Statute of Monopolies*.

Section 101 (1) of the 1949 Act defined 'invention' and 'the Statute of Monopolies', thus:

'Invention' means any manner of new manufacture the subject of letters patent and grant of privilege with section six of the Statute of Monopolies and any new method or process of testing applicable to the improvement or control of manufacture; and includes and alleged invention.

'The Statute of Monopolies' means the Act of the twenty-first year of the reign of King James the First, chapter three, entitled 'An Act concerning monopolies and dispensations with penal laws and the forfeiture thereof'.

## **1.3 THE DEVELOPMENT OF ENGLISH COMMON LAW PRIOR TO 1977**

This Part discusses the English common law with main aim to show the history and development of the view of the UK courts that no patents should be granted to methods of medical treatment. It will be evident at the end of this discussion that most of decisions regarding such patents in the UK were made in 1970s, the time, when a large group of European countries started negotiation of creation the

---

<sup>2</sup> (1914) 31 RPC 235.

<sup>3</sup> *The Wellcome Foundation Ltd v Plantex Ltd* [1979] 2 NZLR 591, 619 (Davison CJ).

<sup>4</sup> *National Research Development Corporation v Commissioner of Patents* (1959) 102 CLR 252, 269.

European uniform law that aimed to deal with the issue of patenting of medical inventions by express prohibition.

### **1.3.1 Methods of medical treatment and manner of manufacture in *C & W's Application*<sup>5</sup>**

The first time a medical procedure patent was considered in the UK was in *C & W's Application*. The relevant statute in this case was the *Patents and Designs Act* 1907 (UK). The definition of invention in s 93 of that Act was essentially in the same terms as s 101 of the 1949 Act, extracted above. To be patentable, the alleged invention had to constitute a manner of manufacture within the meaning of s 93 of the Act, which in its turn referred to the requirement of 'new manufacture' in s 6 of the *Statute of Monopolies*.

C & W applied for a grant of patent in respect of a process for extracting metals from living bodies, and particularly for extracting lead from persons suffering from lead poisoning. Based on established practice,<sup>6</sup> the Patent Office refused a patent on the ground that the alleged invention related simply to medical treatment, and therefore was not a manner of manufacture.

The appeal was heard by the Solicitor-General, Sir Stanley Buckmaster. He first examined the meaning of the phrase 'new manufacture' and concluded that it was something associated with the manufacture or sale of commercial products. This led to the conclusion that an 'invention' within the meaning of the 1907 Act was an invention for a manner of new manufacture that was in some way associated with commerce and trade. In applying this interpretation to the alleged medical treatment invention, the Solicitor-General concluded that the extraction of lead from the body of human beings was not 'a process employed in any form of manufacture or of trade'.<sup>7</sup>

The Solicitor-General also made a point that an invention 'does not merely mean that it must be a product', but 'it may be a ... process that can be used in making something that is, or may be, of commercial value'.<sup>8</sup> He concluded that a medical treatment process could not fit this description. This was the second ground for the decision.

---

<sup>5</sup> *In the Matter of C & W's Application for a Patent* (1914) 31 RPC 235.

<sup>6</sup> *The Wellcome Foundation Ltd v Plantex Ltd* [1979] 2 NZLR 591, 619 (Davison CJ).

<sup>7</sup> *In the Matter of C & W's Application for a Patent* (1914) 31 RPC 235, 236.

<sup>8</sup> *Ibid.*

The Solicitor-General cited no authorities in support of his exclusion of methods of medical treatment from patentability. Rather, the Solicitor General relied on established practice of the Patent Office - to refuse applications merely upon the ground that the alleged invention related simply to medical treatment, which he concluded was sound. Thus, it appears that the only authority of the exclusion of patenting of medical inventions was the practice established by the Patent Office. However, at no point did Lord Buckmaster attempt to ascertain the purpose of s 6 or the meaning of the proviso to s 6, particularly the meaning of 'generally inconvenient'. Instead, the Solicitor-General did no more than endorse what appears to have been represented to him as the Patent Office view (which could be erroneous). Nevertheless, since *C & W's Application* it seems to have been accepted as axiomatic in the UK that there can be no patents for medical treatment.<sup>9</sup>

### **1.3.2 The 'vendible product' rule and its application in *Matter of an Application for a Patent by GEC*<sup>10</sup> (*GEC's Application*) and beyond**

#### **1.3.2.1 *GEC's Application***

The next significant step in the development of UK patent law leading up to the crucial 1970s cases on methods of medical treatment was *GEC's Application*. In this case, decided in 1942, Morton J provided guidance in distinguishing between a method or process that is a manner of manufacture from a method or process that is not. As the consequence, the word 'manufacture' came to be restricted to a vendible products and processes for their production.

The applicant in *GEC's Application* claimed patent protection for the 'improvements in and connected with fire extinguishing'.<sup>11</sup> Five out of ten claims were allowed by the Patent Office. The remaining claims were subsequently amended, but were refused by the Patent Office. On appeal, Morton J, as he then was, expressed certain principles as to the interpretation of the phrase 'manner of new manufacture'. His Honour said:

In my view a method or process is a manner of manufacture if it (a) results in the production of some vendible product or (b) improves or restores to its former

---

<sup>9</sup> The same manner of new manufacture test has been applied in a number of English cases that followed after *C & W's Application*, including *Re BA's Application* (1915) 32 RPC 348 and *Sharp and Dohme Inc v Boots Pure Drug Company Ltd* (1928) 45 RPC 153.

<sup>10</sup> (1942) 60 RPC 1.

<sup>11</sup> *Ibid.*



condition a vendible product or (c) has the effect of preserving from deterioration some vendible product to which it is applied.<sup>12</sup>

In this statement the interpretation of the word 'manufacture' is restricted to a 'vendible product' resulting from the three kinds of activity: a production, an improvement or restoration and preservation from deterioration.

### 1.3.2.2 *Henry Barnato Rantzen's Application (Rantzen's Application)*<sup>13</sup>

The test laid down by Morton J was given an expansive interpretation in the case of *Rantzen's Application* illustrates how the scope of the vendible product test could be given an expansive application. In this case an application for a patent was made for a method of transmitting electrical energy in a particular form either by wireless or over wires. The Patent Office refused to grant a patent on the basis that since the alleged invention was not within the rule which was stated by Morton J in *GEC's Application*, it was not a 'manner of new manufacture'.<sup>14</sup>

On appeal, Evershed J decided the matter in a manner favourable to the inventor. It appears that his Honour had some initial difficulty in applying the vendible product test to the alleged method of transmitting electrical energy. His Honour said:

I find it, therefore, difficult to apply to *electricity* the characteristics of 'vendible product', if by that phrase is meant something which can be passed from one man to another upon a transaction of purchase or sale.<sup>15</sup>

Evershed J went on to refer to the definition in the Shorter Oxford English Dictionary of the word 'product', which included 'that which is produced by any action, operation or work'. His Honour stated that it would not be right to give to the term 'vendible product' a narrow construction by placing undue emphasis on the material requirements,<sup>16</sup> and concluded:

...in the light of present knowledge that electricity or electric oscillation is an entity which, however lacking in material content, can without any violence of language be said to be generated and its characteristics controller... and further to be

---

<sup>12</sup> Ibid, 4.

<sup>13</sup> (1947) 64 RPC 63.

<sup>14</sup> *Barnato Rantzen's Application* (1947) 64 RPC 63.

<sup>15</sup> Ibid, 66 (*Emphasis added*).

<sup>16</sup> Ibid.

transmitted and received. Nor,... can it be said that the notion of electricity as a product which is paid for, is... wholly inappropriate and insensible.

I have therefore come to the conclusion that the appeal should be allowed; that is to say, I do not think that the right of the Applicant to proceed to a grant ought to be altogether barred on the ground that the electric oscillations... are not 'vendible products', and, on that account, not the subject of any manner of manufacture.

*Rantzen's Application* is a valuable example of how the courts were prepared, in some cases, to apply an expansive interpretation of the vendible product test. It shows the necessity of looking at manufacture as a general concept found in the *Statute of Monopolies*. On the facts, the method was held to be a manufacture by interpreting the vendible product requirement in a sense wide enough to include electrical energy, despite its non-material character.<sup>17</sup>

It could be argued that the English tribunals could have taken this expansive approach to the interpretation of the vendible product requirement for all types of patent applications. However, it seems that there was a marked reluctance to do so in some areas. The tribunals remained particularly reluctant to extend patent protection to cover methods of treatment of plants, animals and humans, as can be seen in the following example.

#### **1.3.2.3 Canterbury Agricultural College's Application<sup>18</sup>**

In this case, the applicant's specification was concerned with mixtures to be administered to sheep to improve the wool yield. The Superintending Examiner, Mr Taylor, refused the application, based upon the long established Patent Office practice relating to the treatment of human beings and animals and the decision in the *C & W's Application*. Though the interpretation of manufacture was not expressly considered in this case, clearly, the Superintending Examiner had the vendible product test in mind when he said:

If a claim covers the treatment of an animal in association with a process of working up the immediate product of the treatment, which working-up process is novel and leads unquestionably to a vendible product, the claim is properly allowable.<sup>19</sup>

---

<sup>17</sup> *National Research Development Corporation v Commissioner of Patent* (1959) 102 CLR 252, 272.

<sup>18</sup> (1958) 75 RPC 85.

<sup>19</sup> *Ibid*, 87.

However, he did not see the proposed process as a 'vendible product' and refused the application.

It must be noted that the Patent Office attitude towards patenting of methods of animal treatment was only a practice, not a rule of law, and that Mr Taylor was not bound by it. Although the Solicitor-General in *C & W's Application* had denied a patent for process for the purposes of removing lead from humans, it appears that the situation would have been different if the application had involved the removal of lead from animals, in order to make them more marketable products. His Lordship emphasized that:

I repeat, if the applicant desires to apply for something applicable to merchantable articles like sheep and cows, that may be the subject of different considerations.<sup>20</sup>

Based on Lord Buckmaster's dictum, it was open to Mr Taylor in *Canterbury Agricultural College's Application* to find that the alleged inventive process was not outside the meaning of vendible product. The improvements to the wool yield would clearly make the sheep a more marketable product.

### **1.3.3 First doubts regarding the correctness of the vendible product rule in *Swift & Co's Application*<sup>21</sup>**

Following the decision in the GEC's Application, the vendible product test continued to be applied on multiple occasions, for more than 20 years. Justice Morton's stated intention was to restrict the application of this test to the particular case, not to make an exhaustive rule. But effectively this is what it became. Rantzen's Application illustrates that the vendible product requirement could be interpreted expansively, where necessary. However, more generally it was given a literal interpretation. In particular, methods of medical treatment were considered by the Patent Office as unpatentable, for they did not lead to the manufacture of a 'vendible product' of commercial value. However, with the passage of time, doubt was expressed as to the soundness of this rigid construction. The vendible product test became the subject of extensive criticism.<sup>22</sup>

In 1959, the Australian High Court in *National Research Development Corporation v Commissioner of Patents (NRDC)* took the opportunity to move beyond the restrictions of the vendible product test. The High Court redefined the question more widely as '[i]s this a proper subject of letters patent according to the principles

---

<sup>20</sup> Ibid.

<sup>21</sup> *Swift & Co's Application* [1961] RPC 129.

<sup>22</sup> *Samuel Reitzman v Grahame-Chapman and Derustit Ltd* (1950) 68 RPC 25, 32; *National Research Development Corporation v Commissioner of Patent* (1959) 102 CLR 252.

which have developed for the application of s 6 of the *Statute of Monopolies*?<sup>23</sup> In the following year, the Supreme Court of New Zealand adopted the *NRDC* test in *Swift & Co v Commissioner of Patents*.<sup>24</sup>

The first decision where doubt was expressed about the vendible product test in the UK was *Swift's & Co's Application*<sup>25</sup> (*Swift*). The alleged invention in this case related to a new method of tenderizing meat products through enzymatic action. The tenderizing effect of certain enzymes on meat was well known, as was the injection of such enzymes into animal carcasses to make the meat more tender. In the known method, a pump was used to inject the enzyme into vascular system of the *dead animal*. However, this resulted in non-uniform distribution of the enzyme and non-uniform tenderization.

The applicant invented a new method of distributing the enzyme, utilizing the pumping action of the animal's heart while the animal was *alive*. This new method overcame existing difficulties associated with the known method. The issue was whether the new process was a manner of manufacture within the statutory meaning of that expression.<sup>26</sup>

When the application came before the Patent Appeal Tribunal in England, Lloyd-Jacob J declined to follow the decision of Barrowclough CJ in the Supreme Court of New Zealand *Swift & Co v Commissioner of Patents* relating to the same invention.<sup>27</sup> In that case, Barrowclough CJ held that the fact that an alleged process is a biological or physiological invention is no bar to the grant of a patent, and if the process results in an improved vendible product it is a manner of manufacture and available for patenting. In delivering his judgment Barrowclough CJ followed the High Court of Australia in *NRDC*. In the English decision, Lloyd-Jacob J concluded that:

...the decision under appeal that this application does not qualify for patent protection as a manner of manufacture was, in my opinion, justified, and must be endorsed.<sup>28</sup>

---

<sup>23</sup> *National Research Development Corporation v Commissioner of Patents* (1959) 102 CLR 252, 269.

<sup>24</sup> [1960] NZLR 775.

<sup>25</sup> *Swift & Co's Application* [1961] RPC 129.

<sup>26</sup> *Swift & Co v Commissioner of Patents* [1960] NZLR 775. This decision will be discussed in more detail in Chapter 3.

<sup>27</sup> [1960] NZLR 775.

<sup>28</sup> *Swift & Co's Application* [1961] RPC 129, 134.

On an application to the Divisional Court of Queen's Bench for a writ of certiorari to quash the decision of the Patents Appeal Tribunal,<sup>29</sup> the Divisional Court did not directly address the question of whether a method of tenderizing meat was a method of new manufacture. It decided the application on a preliminary basis, and held that a patent application should not be refused in the first instance unless there existed no reasonable view that the application was within the ambit of the 1949 Act.

After considering the Australian and New Zealand decisions, the court concluded that on the facts, the application before the court was not within the ambit of the 1949 Act, and therefore, the decision on the Appeal Tribunal was wrong in law.<sup>30</sup> Furthermore, the court discussed the desirability of having a homogeneous development of the law in all countries that had adopted the UK system of patent regulation. Parker CJ, in delivering the leading judgment, said:

That desirability must result in a tendency of our Court to follow those decisions if it possible to do so. Accordingly, I have come to the conclusion that approached in that way there is an error of law on the face of the record.<sup>31</sup>

Thus, without explicitly overruling the vendible product requirement and the narrow approach to the manner of new manufacture introduced by Morton J, the decision in *Swift* expressed doubt as to the correctness of this rigid construction, though *NRDC* was not followed directly. The case clearly paved the way for future change. As the years passed, pressure came to be exerted on the Patent Office to grant patents for methods concerned with medical treatment of humans.

#### **1.3.4 One stage further in the frontier of patentability: *United States Rubber Company's Application*<sup>32</sup>**

The patent application at issue in *United States Rubber Company's Application* concerned a process of treating malignant tumour cells by maleuric acid together with a pharmaceutical carrier. The application covered treatment of both animals and human beings. The Superintending Examiner, Mr Taylor, rejected the application but agreed to the filing of an amended specification in which the treatment was to be confined to animals.<sup>33</sup>

---

<sup>29</sup> [1962] RPC 37.

<sup>30</sup> Ibid, 47.

<sup>31</sup> Ibid, 47.

<sup>32</sup> [1964] RPC 104.

<sup>33</sup> *United States Rubber Company's Application* [1964] RPC 104, 107.

During the course of his decision, Mr Taylor considered the applicability of the Australian *NRDC*<sup>34</sup> and the New Zealand *Swift* cases,<sup>35</sup> and said:

Neither the Australian *NRDC* application nor the New Zealand *Swift* application was concerned with medical treatment, and the references to such in the two judgments are few. However, in the former there is a reference to the need for the qualification of a remark made in a very old judgment '*even if only to put aside a process for treating diseases of the human body*': [1961] RPC 142; and at page 145 there is an aside '*The exclusion of methods of surgery and other processes of treating the human body may well lie outside the concept of invention because the whole subject is conceived essentially as non-economic*: see *Maeder v Busch* (1938) 59 CLR 684 at page 706.' I consider, having regard to these remarks, that it would be unreasonable to think of a method of medical treatment of human body as an invention within the meaning of s 101 of the Act.<sup>36</sup>

From the above statement, one can easily see that, while quoting from the Australian judgment the words '*even if only to put aside a process for treating diseases of the human body*', Mr Taylor omitted from the quotation the words '*as they apparently must be put aside*'. It could be argued that he did not fully appreciate the doubt inherent in these words.<sup>37</sup>

Further, in considering the New Zealand *Swift* case,<sup>38</sup> Mr Taylor went on to say:

...I would not now be prepared to say, having regard to the facts of the New Zealand Court judgment, that there could be no reasonable doubt that the treatment of an animal for stimulating or altering a product of its metabolism such as milk or wool was not a manufacture.<sup>39</sup>

From this statement, it appears that Mr Taylor, after considering the New Zealand case, changed his attitude towards patentability of treatments of animals, recalling that in the *Canterbury Agricultural College*<sup>40</sup> case he decided that the process for administration of mixtures to sheep to improve wool yield was not a manner of manufacture.

---

<sup>34</sup> *National Research Development Corporation v Commissioner of Patents* (1959) 102 CLR 252.

<sup>35</sup> *Swift & Co v Commissioner of Patents* [1961] RPC 147.

<sup>36</sup> *United States Rubber Company's Application* [1964] RPC 104, 105 (*Emphasis added*).

<sup>37</sup> *The Wellcome Foundation Ltd. v Plantex Ltd. and other* [1974] RPC 514, 529 (Witkon J).

<sup>38</sup> *Swift & Co v Commissioner of Patents* [1961] RPC 147.

<sup>39</sup> *United States Rubber Company's Application* [1964] RPC 104, 106.

<sup>40</sup> (1958) 75 RPC 85.

Mr Taylor admitted that the earlier decision was based solely on the practice of the Patent Office, but in view of the Australian and New Zealand decisions he gave new significance to the remark of the Solicitor-General in *C & W's Application*, where he said that a process which makes animals a better marketable product is subject to different considerations. Thus, he clearly distinguished the above process from the process concerned with medical treatment of humans.<sup>41</sup>

Mr Taylor also distinguished between the tenderized meat product of the New Zealand *Swift* process and medical treatment of a living animal. However, he concluded, after reference to *Swift*, that he was unable to say of the medical treatment of animals that on no reasonable view could it be said to be an invention within the meaning of s 101 of the 1949 Act.<sup>42</sup> Consequently, he agreed to the filing of an amended specification in which the treatment was to be confined to animals.

It is interesting to note that, although Mr Taylor made reference to *C & W's Application* and to *NRDC*, he did not consider the effect of the *NRDC* decision upon the grounds for refusal given in the *C & W's Application*. Moreover, the development in the law was not into account in evaluating *C & W's Application*.<sup>43</sup>

Thus, it can be suggested that *United States Rubber* did not establish any clear ground for refusing a patent for medical treatment. The decision, rather, advanced the frontier of patentability one stage further. This is because the Examiner allowed an application for an invention providing for medical treatment to proceed to a grant if the complete specification deleted reference to treatment of humans, and was therefore applicable solely to animals.

### **1.3.5 Release from the restrictions of the vendible product test by English courts: *Schering AG's Application*<sup>44</sup> (*Schering*).**

Another seven years passed before the easing of the restrictions of the vendible product test was accepted in England, in *Schering*.<sup>45</sup> As Witkin J stated in *Wellcome Foundation Ltd v Plantex Ltd*,<sup>46</sup> the importance of the judgment in this case lies more in the reasons rather than in the final result. The result in *Schering* was that the Patents Appeals Tribunal allowed a patent application for a method of contraception to proceed upon the grounds that, although patents for medical

---

<sup>41</sup> (1914) 31 RPC 235, 236.

<sup>42</sup> *United States Rubber Company's Application* [1964] RPC 104, 106.

<sup>43</sup> *Wellcome Foundation's (Hitchings's) Application* (New Zealand) [1979] 2 NZLR 591, 618.

<sup>44</sup> [1971] 3 All ER 177.

<sup>45</sup> *Ibid.*

<sup>46</sup> [1974] RPC 514, 531.

treatment in the strict sense of curing or preventing disease had to be excluded under the 1949 Act, the claimed method of contraception did not appear to fall within that prohibition. The reasons of the Patents Appeal Tribunal are important because in stating them the court considered the main question of whether the exclusion of methods of medical treatment from patentability had a firm basis.

At the first instance, the Superintending Examiner rejected the application as he considered it to be a method of treatment of the human body. On appeal, Whitford J of the Patents Appeal Tribunal stated that neither the 1949 Act nor the preceding legislation provided that a process for the treatment of human beings was regarded as incapable of patent protection. Whitford J confirmed that the refusal had been based solely on the Patent Office practice that such process has never qualified as a manner of new manufacture within s 6 of the *Statute of Monopolies*. Based on that practice, for more than 50 years, inventions in the field of contraception had been denied the royal prerogative of granting monopoly.

The court made it clear that it was no longer bound by the restrictive concept of invention adopted by earlier case law and said:

It may be thought surprising that the definition of 'invention' in 1971 should be based on words in a statute in 1623, but the policy of the courts has always been to avoid putting too precise an interpretation of the word 'manufacture' and some observations in the judgment of the High Court of Australia in *National Research Development Corporation's Application* (1961) RPC 134 at 142 are as apposite to the development of the law in this country as they are to the development of the law in Australia.<sup>47</sup>

Whitford J then went on to state:

Thought the test of 'vendible product' may often be a useful test, it has long been accepted that it is not a conclusive test which must be passed if a patent is to result.<sup>48</sup>

Further, Whitford J repeated that today it is recognized that the vendible product test, though sometimes useful, is not conclusive.<sup>49</sup> Notwithstanding that the alleged invention did not satisfy the vendible product test, the court acknowledged that a

---

<sup>47</sup> *Schering AG's Application* [1971] RPC 337, 340.

<sup>48</sup> *Ibid*, 341.

<sup>49</sup> *Ibid*, 344.



process involving a chemical treatment *was an invention*.<sup>50</sup> The court also recognised the role of the patent system in encouraging the development of new pharmaceutical inventions, stating that:

It is plainly arguable on ethical grounds that there should be no patent protection on the medical field at all. In this country, however, it has long been recognized that persons producing new pharmaceutical substances or curative devices can secure patent protection for them. Any unwarrantable exploitation in the medical field is supposed to be guarded against by the compulsory licence provisions of s 41 of the Patents Act 1949...<sup>51</sup>

Clearly then, the court recognized that costly research on an ever-increasing scale might be necessary in the field of medical treatment. However, the court expressed the opinion that it was for legislature to review the question whether the methods of medical treatment should be patentable, remarking that:

...it may well be desirable that the legislature should review the question whether applications for patents for medical treatments generally or to some less, and, if so, to what, extent should be permitted. An opportunity to do this will arise in the near future if and when the Banks Committee report is implemented.<sup>52</sup>

In considering the terms of the 1949 Act, the court felt compelled to accept the practice of the Patent Office as good law, stating that claims to methods of medical treatment must be considered as being excluded from the scope of the Act.

However, the court was not persuaded that it necessarily followed that claims to a method of contraception should be rejected. As the emphasis had been upon the element of 'treatment of a disease', the court took the view that treatment for the prevention of pregnancy was outside the area of therapeutic treatment of the human body, since it could not be regarded as a 'medical' treatment or a treatment to cure or prevent disease. Thus, Whitford J in *Schering* accepted a narrow interpretation of the meaning of 'medical treatment', and allowed a patent application for a method of contraception.

The decision in *Schering* has significance. Firstly, the court distinguished in kind a non-patentable process for treating the diseases of the human body from a patentable contraceptive process. In rejecting any general exclusion for processes

---

<sup>50</sup> Ibid.

<sup>51</sup> Ibid, 340.

<sup>52</sup> Ibid, 344.

of medical treatment, the court applied the principle enunciated by the High Court of Australia in *NRDC*.<sup>53</sup> The process was in the field of the 'useful arts' (as opposed to the 'fine arts'), it was of commercial value because it would produce a result that people would be prepared to pay for, and in the present state of public opinion, the result was considered desirable. As a consequence, therefore, the court considered the method of contraception as a patentable invention.

Secondly, in interpreting the word 'manufacture', Whitford J did not apply a rigid statutory formula, but followed *NRDC* in making an inquiry into the scope of the subject matter of letters patent protected by the s 6 of the *Statute of Monopolies*. Thus, *Schering* was the first judgment in the UK where the court accepted the broad construction of manner of manufacture first formulated by the High Court of Australia in *NRDC*. However, this change in approach did not release methods of medical treatment from the restriction against their patentability.

### 1.3.6 Applications of the *Schering* case

#### 1.3.6.1 *Calmic Engineering Co Ltd's Application*<sup>54</sup> (*Calmic Engineering*)

In 1972 another unsuccessful attempt was made to patent a method of treatment for the human body. In *Calmic Engineering*<sup>55</sup> the patent application in issue concerned a new method of purifying blood using an apparatus for removing toxic substances from the blood. The Superintending Examiner, Mr Mirams, refused to allow the claim as it did not relate to an invention as defined in s 101 of the 1949 Act. Although the claim was concerned simply with purification of the blood and did not mention the treatment of a patient, the interpretation of patent specification led to the conclusion that it was indeed a method of treatment claim.

In his reasons for the decision, Mr Mirams admitted that it appeared 'somewhat illogical' to allow claims to an apparatus and at the same time disallow claims to the normal use of that apparatus.<sup>56</sup> However, he did not give any logical explanation for such an approach.

On appeal to the Patent Appeals Tribunal, Graham J, in a very short judgment, held that the claim was broad enough to cover the process when 'it is being carried out by a doctor or hospital as applied to a patient suffering from a kidney

---

<sup>53</sup> See *National Research Development Corporation v Commissioner of Patents* (1959) 102 CLR 252, 269, which is discussed in more detail in Chapter 4, Parts 4.4.2 and 4.5.1.2.

<sup>54</sup> [1973] RPC 684.

<sup>55</sup> *Ibid.*

<sup>56</sup> *Ibid.*, 685.

disease'.<sup>57</sup> Therefore it was clearly a method of medical treatment, and thus unpatentable. Graham J said:

[It] was quite clear to the hearing officer also as it seems to me from his decision. He came to his conclusions on the basis that the claim was for a method of medical treatment as patents have not been allowed to cover up to the present date. Whitford J and I in the *Schering* case made it clear that in our view patents as the present time should not be granted for such a medical treatment.<sup>58</sup>

#### 1.3.6.2 *Dow Corning Corporation (Bennett's) Applications*<sup>59</sup>

In this case the applicant discovered that certain fluoroalkylsilicon compounds were capable of effecting an alteration in the androgenic capacity of male mammals when administered in any pharmacologically acceptable manner. The claimed invention related to a package containing a well-known substance (which therefore was not a manner of new manufacture), together with the instructions of such administration.

The appeal case was heard by Whitford J again, who held that the only basis upon which it could be suggested that there was some disclosure of a manner of manufacture, was the instructions of administration of the compound. However, the instructions were viewed as a claim to a process, which covered the treatment of humans, and so was not patentable. Whitford J noted that in the case of *Schering* he had made certain observations as to the illogical position that exists under which it is possible to secure patent protection for new drugs which are going to be used in treatment but not possible to secure patent protection for methods of treatment as such.<sup>60</sup> However, his Honour was unprepared to discuss this any further, concluding that:

In truth, what the applicants would like to do is to secure protection which is effectively going to give them a monopoly which must, as I see it, have this affect, that it will give them a monopoly in relation to medical treatment of human beings. For the application it was said, quite frankly, that the importance if this in the field of treatment of human beings is that the substances can be used to treat certain diseases.<sup>61</sup>

---

<sup>57</sup> Ibid, 687.

<sup>58</sup> Ibid, 687.

<sup>59</sup> [1974] RPC 235.

<sup>60</sup> Ibid, 238.

<sup>61</sup> Ibid, 238.

Thus the instructions for administering the compound were viewed as a claim to a process of medical treatment, therefore, not the proper subject matter of patent. This view is somewhat incongruous. The instruction itself cannot be a treatment. The drugs, on the other hand, are more likely to be a treatment than instructions. Indeed, in most cases, drugs are exclusively used for and will result in a treatment of disease, and yet they are considered a patentable subject matter. If the *final result* of the administration of the substance determines its patentability, then the instructions to the treatment, the drugs and treatment must equally enjoy a patent protection as they produce the same result: a changed condition in the human body.

### **1.3.7 The first applications of the proviso to s 6 of the *Statute of Monopolies* by the English courts: *Eli Lilly & Company's Application*<sup>62</sup>(*Eli Lilly*)**

In 1974 yet another unsuccessful application was made to patent a method of medical treatment of humans in *Eli Lilly*. In this case, the court, for the first time, based the exclusion on the basis of the public policy proviso to s 6 of the *Statute of Monopolies*.

The applicant discovered that certain chemical compounds, which were known *per se*, had unsuspected anti-inflammatory properties that could be used with beneficial effect in the symptomatic treatment of various inflammatory conditions in humans and animals.

The Patents Appeal Tribunal, constituted by Graham and Whitford JJ, held that since the chemical compounds were not new, the only possible claim was to a novel manner of use. However, since the novel manner of use was treating disease in humans, it was therefore not patentable. The court stated that regardless of other changes in the law,<sup>63</sup> the restrictions on medical treatment patents still applied. Thus, the refusal by the court to allow patent protection appears to have been based not upon the argument that the application did not involve a method of manufacture, but on the basis that such a method of manufacture was not patentable in respect of medical treatment of humans.

The court confirmed that the law at the present time stood, so that no patent could be granted for a new use that sought to be claimed as a cure or disease prevention in human beings. *Schering* was cited as authority on this point. Although the court

---

<sup>62</sup> [1975] RPC 438.

<sup>63</sup> For example, a change in the concept of 'manner of manufacture' to meet the needs of the modern age, formulated by the Australian High Court in *NRDC*.

regarded the prohibition as 'technically anomalous and therefore illogical',<sup>64</sup> it went on to explain the legal justification for such illogical refusals of medical treatment patents, stating that 'the reasons for such an exclusion appear to us to be based in ethics rather than logic...'.<sup>65</sup>

The court reached this conclusion after a discussion of the proviso to s 6 of the *Statute of Monopolies*, which declared the invention void if it was 'contrary to the law or mischievous to the State by raising prices of commodities at home, or hurt of trade, or generally inconvenient.' Graham and Whitford JJ admitted that the 'generally inconvenient' exception had never previously been used as the basis for refusing medical treatment applications. But they concluded that the proviso at the end of s 6 '[could] no more be ignored', and in every case where the issue of patentability arises, it has to refer to s 6 to answer the question, formulated by the High Court of Australia in *NRDC* as to whether 'this then a proper subject of letters patent according to the principles which have been developed for the application of s 6 of the *Statute of Monopolies*?'

Therefore, for the first time the court justified the soundness of its refusal to allow patenting of medical treatment by reference to public policy<sup>66</sup>. Though Graham and Whitford JJ adhered to public policy, the court made clear that it did so with respect for the legislative process: '... if there is to be a change of policy, which would appear to us to be sensible, this ought in our view to be effected by legislation rather than by interpretation'.<sup>67</sup>

---

<sup>64</sup> [1975] RPC 438, 444.

<sup>65</sup> Ibid, 445.

<sup>66</sup> The question about the relation between ethics and public policy has a long tradition in Western philosophy. It dates back to classic Aristotelian philosophy and continues to be debated in modern traditions such as Hobbes and Kant. It is beyond the scope of this thesis to deal with the difference between ethics and public policy. Nor it is the purpose to analyse the relation between these two concepts. Rather, it is sufficient to say that ethics has become an integral part of the political, legal, and the social life. Compared to the limited Aristotelian conception of ethics and public policy, in modern democracies ethics extends into such contexts as the parliament, law, academia and media. Indeed, when considering patenting of methods of medical treatment courts often use terms 'ethics', 'morality', and/ or 'public policy' without any apparent intention to make any clear distinction in their meanings (see, eg *Eli Lilly & Company's Application* [1975] RPC 438; *Anaesthetic Supplies Pty Ltd v Rescare Ltd* (1994) 50 FCR 1; *Joos v Commissioner of Patents* (1972) 126 CLR 611). The most recent decisions suggest that the courts tend to refer to 'public policy' as a concept that embraces both ethics and/or morality (see, eg *Bristol – Myers Squibb Co v F H Faulding & Co Ltd* [2000] FCA 316). For the above reasons this thesis deals with ethics, morality, and/ or public policy by reference to one term - public policy.

<sup>67</sup> Ibid.

## 1.4 CONCLUSION

This Chapter has revealed a consistent pattern of exclusion of methods of medical treatment in the UK case law, from *C & W's Application* in 1914 onwards. However, the rationale for the exclusion has changed over time in parallel with the changes to the interpretation of the manner of manufacture requirement. The position of the UK case law immediately prior to the 1977 Act on the issue of patentability of medical treatment could be summarised as follows:

1. Methods of medical treatment did not come within the definition of 'invention' as meaning 'any manner of new manufacture the subject of letters patent and grant of privilege within s 6 of the *Statute of Monopolies*.'
2. There was no actual judicial authority in the UK, which had stated that such methods were patentable.
3. A non-patentable process for treating the diseases of the human body was distinguishable in kind from a patentable contraceptive process. The latter process was considered to be in the field of the 'useful arts' and former of the 'fine arts'.<sup>68</sup>
4. Since the foundation in the *C & W's Application* has been removed by subsequent decisions in *NRDC*, *Swift* and *Schering*, English courts started searching for alternative basis for refusal of granting patents for methods of medical treatment. The basis was found in the proviso to s 6 of the *Statute of Monopolies* which provides that the monopolies shall not be 'generally inconvenient'. *Eli Lilly* is the first decision whether the proviso to s 6 of the *Statute of Monopolies* was ever considered by the courts. The public policy argument from the proviso to s 6 of the *Statute of Monopolies* was found to be a new basis for the refusal of the invention in question and paved the way for future refusals.

It is interesting to note that most of the decisions heard in 1970s were decided by the same judge of the Patents Appeal Tribunal, Whitford J.<sup>69</sup> From this fact, one could suggest that the exclusion of such methods was substantially influenced by a subjective view of one judge.

---

<sup>68</sup> *Schering AG's Application* [1971] 3 All ER 177.

<sup>69</sup> *Ibid*; *Dow Corning Corporation (Bennett's) Applications* [1974] RPC 235; *Eli Lilly & Company's Application* [1975] RPC 438; *Upjohn Company (Robert's) Application* [1977] RPC 94.

However, it is conceded that such methods have long been excluded from patentability by an established practice of the Patent Office and the case law that followed the decision in *C & W's Application*.<sup>70</sup> The fact that methods of medical treatment had been considered to be unpatentable for so long meant that it would have been a bold step for Whitford J to pass over the barrier of non-patentability and change this situation. Although his Honour expressed doubt regarding the legal and political legitimacy of this exclusion from patentability, he was of the opinion that elimination of this exclusion exceeded the competencies of the courts and was regarded as being a task for the legislature.<sup>71</sup>

The legislature was given the opportunity of addressing this issue in the new 1977 *Patents Act* (UK). However, it was not entirely free to decide this issue in isolation, because the main driver for new legislation was harmonisation of UK law with European law. The European position with regards to patenting of methods of medical treatment forms the basis of the next Chapter.

---

<sup>70</sup> (1914) 31 RPC 235.

<sup>71</sup> [1971] RPC 337, 344.

## CHAPTER 2: THE EUROPEAN PATENT CONVENTION AND THE EUROPEAN COUNTRIES

### 2.1 INTRODUCTION

This Chapter provides an analysis of the key aspects of patent law in Member States of the European Patent Convention,<sup>1</sup> as it relates to patenting of methods of medical treatment. The discussion in this Chapter is important because it marks a shift away from reliance on s 6 of the *Statute of Monopolies 1624* (the ***Statute of Monopolies***) in UK law. It illustrates how courts deal with express exclusions from patenting for method of medical treatment and how such exclusions can be avoided by creative drafting of patent applications. This also provides an interesting contrast to the approach taken in Australia where there are no express exclusions.<sup>2</sup>

This Chapter starts with a discussion of the outcomes of an inquiry into patent law reform in the UK in 1970, followed by an analysis of the development and operation of the European Patent Convention and its influence on the laws of member states. Chapter 1 showed that until 1974 there had been no court decision in the UK that had upheld a claim related to a method of medical treatment of a human body to cure or prevent disease. Indeed, there had been no court decision to this effect in any of the other prospective member states<sup>3</sup> of the European Patent Convention either.<sup>4</sup>

Though the patent courts of other European countries did not deal so intensively with the issue of patentability of methods of medical treatment as English courts, the general practice was similar.<sup>5</sup> For example, a grant for patent protection in France and Italy would be denied if the alleged invention lacked industrial character.<sup>6</sup> In Austria<sup>7</sup> and Switzerland<sup>8</sup> one of the ground for refusal of medical inventions was public policy considerations.

---

<sup>1</sup> Convention on the Grant of European Patents (European Patent Convention) 5 October 1973, 1065 U.N.T.S. 199, E.T.S. No 16, Cmd. Munich. The Convention entered into force on 7 October 1977 for the following first countries: Belgium, Germany, (then West Germany), France, Luxembourg, Netherlands, Switzerland and UK, and on 1 May 1978 for Sweden.

<sup>2</sup> See Chapter 4.

<sup>3</sup> A small exception to that is a fact that, during the early years of the German Patent Office (until 1904), a few patents were granted for medical methods. See further discussion.

<sup>4</sup> White, 'Patentability of Medical Treatment – Wellcome Foundation's (Hitching's) Application' (1980) 2 *European Intellectual Property Review* 364.

<sup>5</sup> Rainer Moufang, 'Methods of Medical Treatment Under Patent Law' (1993) 24 *International Review of Industrial Property & Copyright Law* 18, 26.

<sup>6</sup> Moufang, above n 3, 27.



One country where there were some notable decisions on patenting of methods of medical treatment prior to the European Patent Convention was Germany. During the early years of the German Patent Office, in 1890-1904, a few patents had been granted for medical methods. These included patents for a method of removing deeper stitches from wounds;<sup>9</sup> a method for treating curvature of the human spine;<sup>10</sup> a method of removing magnetized objects from the eye or another part of the body;<sup>11</sup> and a method of transilluminating parts of the body using X-rays.<sup>12</sup>

However, following the decision of the Board of the Imperial Patent Office in 1904,<sup>13</sup> Germany changed its attitude towards patentability of medical inventions. The Patent Office stated that the treatment of humans was an area for which patent protection had not been created by the legislature. This case established the precedent that an industrially applicable invention could only be assumed to exist where raw material was mechanically or chemically treated or processed.

In 1967 the German Federal Supreme Court delivered a judgment that had a lasting influence on future European patent law. In the *Glatzenoperation* case,<sup>14</sup> the court emphasized that public health was a key element of public welfare, which must be safeguarded by the State. The court concluded that the duties placed upon medical doctors in order to maintain human health constitute a social-ethical reason why the medical profession is not a trade and why a doctor must be free in the use of methods of medical treatment.<sup>15</sup> It was held in this case that the criterion of industrial applicability 'could serve as the dogmatic anchor for the exclusion of medical methods'.<sup>16</sup> It will be seen later in this Chapter that this criterion was to become the basis for the exclusion of medical methods in the European Patent Convention.

Although the patentability of medical treatments was blocked following the *Glatzenoperation* case, case law in Germany in the field of pharmaceutical product

---

<sup>7</sup> Decision of the Appeal Board of the Austrian Patent Office of May 29, 1973, 1974 GRUR Int 180.

<sup>8</sup> Decisions of the Swiss Federal Court, September 24, 1946, 72 BGE I, 368, 1951 GRUR 283; February 4, 1975, 101 BGE Ib 18, 1975 SchwPMMBI. I 33, 1975 GRUR Int 314.

<sup>9</sup> German patent No. 150666.

<sup>10</sup> German patent No. 150699.

<sup>11</sup> German patent No. 155294.

<sup>12</sup> German patent No. 156389.

<sup>13</sup> *Badewasser* (1904) BlfPNZ 4.

<sup>14</sup> Decision of the Federal Supreme Court of September 26, 1967, 48 BGHZ 313, 1968 GRUR 142.

<sup>15</sup> *Glatzenoperation* Federal Supreme Court, 1968 GRUR 142, 146.

<sup>16</sup> See critical point of view expressed by Friedrich-Karl Beier, 'Future Problems of Patent Law' (1972) 3 *International Review of Industrial Property & Copyright Law* 423, 431.

patents proved to be much more generous.<sup>17</sup> At the same time, however, all pharmaceutical inventions in Italy were deemed to be unpatentable. Also, pharmaceutical products in France could only be patented by way of a special medicament patent, for which there were strict provisions for sufficiency of disclosure.<sup>18</sup>

## 2.2 THE UNITED KINGDOM: BANKS COMMITTEE REPORT

In the UK, in parallel with developments in the case law, the political debate about the appropriate scope of patenting was intensifying. In 1970 the Banks Committee in its Report on the British Patent System (the *Banks Report*) considered the patentability of a process consisting of using a known compound for treating human beings medically.<sup>19</sup>

Notwithstanding arguments presented by unsuccessful patent applicants on many occasions, *inter alia*, that lack of patent protection in the field of medical treatment of humans had resulted in insufficient research and development effort being put into discovering of new chemical compounds and new uses for treatment of disease, the Committee decided that an extension of patent protection would not be desirable. Instead, the Committee recommended that patents should not be granted for processes for treating human beings with known substances. The ground for this recommendation was simply the fact that the majority of countries did not permit patents for a new medical use of a known substance, and that the UK should follow suit.<sup>20</sup> According to the Committee, since new chemical compounds and processes for making such compounds were already patentable, the only additional type of invention that could be patentable would be a method using a known compound in a known form against a disease for which it was not previously thought to be effective. In the view of the Committee, a claim for such an invention would have to specify the conditions against which the compound was effective and include instructions for its use.<sup>21</sup> As a consequence, it would allow patents for the *treatment* of human beings, and this, according to the Committee, was undesirable.

---

<sup>17</sup> Decision of the German Federal Supreme Court of January 20, 1977, 68 BGHZ 156, 9 *International Review of Industrial Property & Copyright Law* 42 (1978)-Benzene sulfonyl urea; also decision on the Federal Supreme Court of June 3, 1982, 14 *International Review of Industrial Property & Copyright Law* 283 (1983)-Sitoserylglucosides.

<sup>18</sup> Alan W White, 'Patentability of Medical Treatment Claims – The Nimodipin Cases' (1984) *European Intellectual Property Review* 38.

<sup>19</sup> The British Patent System (1970) Cmnd. 4407, (the Report) para 237-40.

<sup>20</sup> Report, Cmnd 4407, para 237-240.

<sup>21</sup> *Ibid.*

No explanations were given as to why it would be undesirable to extend a patent protection to processes of medical treatment. The Committee was aware of the decisions that had concluded that a process of medical treatment is not the proper subject matter for a patent monopoly. However, it is noteworthy that at the time of the Banks Report, the question of what was 'a proper subject for a patent monopoly' was 'whether the invention was a manner of new manufacture within s 6 of the *Statute of Monopolies*'.<sup>22</sup> At that time, there had been no judgment of an English court that decided whether process for medical treatment fell outside the ambit of s 6.<sup>23</sup> In particular, no judgment had addressed the question of whether or not methods of medical treatment were 'mischievous to the State' or 'generally inconvenient'. As such, the statements made in the Banks Report appear to be over simplification. As Chapter 1 revealed, the long established Patent Office practice that methods of medical treatment were not associated with commerce and trade, had been removed by subsequent decisions. Therefore, at the time of the Report, *there was no legal ground* on which to base a refusal for patenting of such methods, although it is conceded that subsequently Whitford J found such a ground in the general inconvenience provision in s 6 of the *Statute of Monopolies* in *Schering* and subsequent cases.<sup>24</sup>

It is submitted that the Banks Report included various errors of law and fact<sup>25</sup>, one of which was the omission of details of the true position in the United States, which had been clear since 1954. In that year the Patent Office Board delivered the decision of *Ex parte Scherer*,<sup>26</sup> which is discussed in Chapter 3. In that case, the United States Board of Patent Appeals held that medical processes were patentable subject matter.<sup>27</sup> Since then, patents with claims to human medical treatment have been frequently issued in the United States. In addition, the Report did not mention that in one European country, namely Belgium, a patent had been granted to medical processes for the treatment of humans.<sup>28</sup>

The main mandate of Banks Committee was to investigate the UK patent system and to deliver its opinion on that system. In reality, the Committee simply made an

---

<sup>22</sup> *National Research Development Corporation v Commissioner of Patent* (1959) 102 CLR 252.

<sup>23</sup> White, above n 2.

<sup>24</sup> See *Schering AG's Application, Eli Lilly & Company's Application* [1975] RPC 438; *Upjohn Company (Robert's) Application* [1977] RPC 94.

<sup>25</sup> See critical point of view expressed by White, above n 2.

<sup>26</sup> *Ex parte Scherer* (1954) 103 USPQ 107.

<sup>27</sup> *Ibid*, 110.

<sup>28</sup> JW Baxter, *World Patent Law and Practice* (1968), 232. Baxter clearly said: "The following countries are the only important ones in which one can obtain claims to medical processes for the treatment of man: Belgium, South Africa and USA".

observation of the situation with regards to this matter in other European countries without fully investigating the legal principles that form the backdrop to patentability of inventions in the UK. Since the majority of other European countries did not permit patents for new medical uses of known substances,<sup>29</sup> the Committee took the view that the UK should remain in line with this majority. Moreover, after an observation of English case law, the Committee simply followed the decisions of the courts and did not form its own opinion based on relevant legal principles, as it was mandated to do. It appears therefore, that the Committee did not fulfill its initial requirement.

The decision of the Banks Committee not to recommend patenting of methods of medical treatment had significant consequences for UK patent law. As a consequence of the Committee's recommendation to the UK Parliament, it was decided to expressly exclude methods of medical treatment from patentability by the provisions of s 4(2) of the *Patents Act 1977* (UK) (the **1977 Act**). It is submitted that but for the Banks Report, the UK Parliament might well have changed its attitude towards patentability of medical treatment, following the suggestion of Whitford J to reconsider the appropriateness of such an exclusion. It is submitted that this was the right time for the UK legislature to ask two fundamental questions. First, what is the true aim and object of the patent system? Secondly, is it fair that a reward for service to the public is denied to those who spent their lives, passion and expertise in looking for and finding a cure for a disease? At that time the UK Parliament had an opportunity to change its attitude towards patentability of medical treatment, but lost that opportunity.

It is acknowledged that the UK Parliament was somewhat constrained in its capacity to reform patent law because of the UK's obligations under the European Patent Convention, of which it was a Member State. However, it is submitted that had the Banks Committee supported patenting of methods of medical treatment, the UK could have played a more influential role in drafting of the European Patent Convention. For instance, a case could have been made for providing Member States with the liberty to decide for themselves whether or not to exclude certain subject matter, including methods of medical treatment.<sup>30</sup>

---

<sup>29</sup> Report, Cmnd 4407, para 237-40.

<sup>30</sup> This is the case in the *Agreement on Trade-related Aspects of Intellectual Property*, Articles 27.2 and 27.3 [1995] ATS 12 (entered into force 15 April 1994)

## 2.3 DEVELOPMENT OF EXCLUSIONARY PROVISIONS IN THE EUROPEAN PATENT CONVENTION

The European Patent Convention (*EPC*) was signed in Munich in 1973, and came into effect in 1978. Shortly after signing the EPC, Member States commenced adjusting their legal systems in accordance with European uniform law, and Art 52(4) was largely adopted. For example, the UK, Germany and France included mirror provisions of Art 52(4) and declared excluded methods as not industrially applicable.<sup>31</sup> Denmark, Italy and Sweden treated them as non-inventions.<sup>32</sup> Switzerland declared excluded methods as legal exceptions to patenting.<sup>33</sup>

Art 52(4) of the EPC reads as follows:

(1) European patents shall be granted for any inventions which are *susceptible of industrial application*, which are new and which involve an inventive step.

(4) *Methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practiced on the human or animal body shall not be regarded as inventions which are susceptible of industrial application* within the meaning of para 1. This provision shall not apply to products, in particular substances or compositions, for use in any of these methods.

*(Emphasis added)*

Before considering the exclusionary scope of Art 52(4), it is necessary to be familiar with the historic roots of the exclusion of medical treatment, in order to understand how this specific exclusionary provision was developed.

There can be little doubt that drafting of Art 52(4) of the EPC was strongly influenced by the Strasbourg Convention on the Unification of Certain Points of Substantive Law on Patents for Invention (***Strasbourg Convention***) of November 1963.<sup>34</sup> The contents of Art 52(4) were not formulated until after the Strasbourg Convention. The first documents that expressed the possibility of an exception for

---

<sup>31</sup> Section 4(2) *Patents Act* (UK); Section 5(2) *Patents Act* (Germany); Article 6(4) *Patents Act* (France).

<sup>32</sup> Section 1(3) *Danish Patents Act*; Section 12(4) *Italian Patents Act*; Section 1 *Swedish Patents Act*.

<sup>33</sup> Section 2(b) *Swiss Patents Act*.

<sup>34</sup> Moufang, above n 3, 27. The Strasbourg Convention is a treaty signed by Member States of the Council of Europe on November 27, 1963 in Strasbourg, France. It entered into force on August 1, 1980 and led to a significant harmonization of patent laws across European countries. The Strasbourg Convention established patentability criteria by specifying on which grounds inventions can be rejected from patentability. The main intention of Convention was to harmonize European patent law. Yet this Convention is quite different from the EPC which establishes an independent system for granting European patents.

methods of medical treatment first appeared in the EC Committee documents in 1964.<sup>35</sup>

Another international document, the 1970 Patent Cooperation Treaty (*PCT*), in particular r 39.1, is also likely to have been highly influential in the exclusion of medical methods.<sup>36</sup> R 39.1 included a list of objects of applications for which the International Searching Authority was not obliged to conduct a search on the basis of unpatentability of those objects. The list in r 39.1(iv) contained 'methods for treatment of the human or animal body by surgery or therapy, as well as diagnostic methods.' As a consequence, the first draft of the EPC in 1970<sup>37</sup> contained Art 9(2)(e), which declared methods for the treatment of the human or animal body by surgery or therapy and diagnostic methods as non-patentable inventions.

In 1972 the French delegation suggested that the term 'diagnostic methods' be clarified by the precise phrase 'applied to the human or animal body', since technological development had resulted in diagnostic methods that lacked a specific medical character.<sup>38</sup> Following that suggestion, the term was clarified.

Later, during the Munich Diplomatic Conference, the German delegation made a successful proposal to clarify that medical methods did in fact constitute actual inventions, but lacked industrial applicability.<sup>39</sup> It is clear that this proposal was made so that the EPC would be compatible with the *Glatzenoperation* decision,<sup>40</sup> which had determined national German patent law since 1968. Subsequently, methods for the treatment of the human or animal body by surgery or therapy and diagnostic methods were deleted from the list of non-inventions and placed in the newly created para 4 of Art 52.

Moreover, upon the instigation of the Dutch delegation, which was concerned that there might be future arguments over the disadvantage of the patentability of medical appliances or instruments,<sup>41</sup> the second sentence of para 4 of Art 52 was amended. It clarified that it was not limited to substances and compounds only, but included products in general.

---

<sup>35</sup> Document (EEC) 11821/IV/64 of December 7, 1964, published in *Historical Documentation Relating to the EPC*, (Munich, 1985) Vol.10E.

<sup>36</sup> Moufang, above n 3.

<sup>37</sup> Published in *Historical Documentation Relating to the EPC* (Munich, 1985) Vol 15 D+E+F.

<sup>38</sup> Document BR/135/72 of March 15, 1972, Published in *Historical Documentation Relating to the EPC* (1985, Munich) Vol 12 E.

<sup>39</sup> Government of the Federal Republic of Germany, *Minutes of the Munich Diplomatic Conference for the Setting up of a European System for the Grant of Patents* (1977) 28, No.23, 28 (the Minutes); Moufang, above n 3.

<sup>40</sup> *Glatzenoperation* Federal Supreme Court, 1968 GRUR 142.

<sup>41</sup> See the Minutes, above n 37; Moufang, above n 3.

The final draft included almost all proposals of the negotiating States. As is the case with practically all international instruments, the EPC was formulated as a compromise among the existing laws of the States, which arguably, harmonized patent laws across European countries. Regarding the exclusion from patentability of methods for treatment of the human or animal body, for example, Alan White remarks that the exclusion was a product of political pressure to curb patent protection in the field of medicine, and the absence of clear law permitting patents to human medical treatment in any of negotiating States.<sup>42</sup>

Art 52(4) has been criticized for perpetuating the 'legal fiction' that methods of treatment of a human body are not susceptible of industrial application.<sup>43</sup> Its first sentence excludes from patentability such methods even if they satisfy the requirements of novelty, inventive step and industrial applicability. Consequently, notwithstanding that the wording of Art 52(4) implicitly recognises that such methods are in fact susceptible of industrial application, they will not be regarded as inventions anyway. It could be argued therefore that the exclusion from patentability of methods for treatment is artificial.

## 2.4 THE EXCLUSIONARY SCOPE OF ART 52(4) EPC

Medical inventions cases heard by the European Patent Office (*EPO*) Boards of Appeal (the *Boards of Appeal*) and by the UK Patent Office necessarily involve reference to Art 52(4) of the EPC and its equivalent in the 1977 Act and in the patent legislation of other Member States. This part of the thesis will present a discussion of the scope of excluded subject matter for the purposes of these provisions. The discussion will provide a summary of the UK view, adopted by the UK Patent Office and the English courts under the 1977 Act, and also a review of the case law of the Boards of Appeal.

The provisions covering patentability in the field of medical inventions are found in Ss 1(1), 2(6) and 4 of the 1977 Act and Arts 52(1), 52(4), 54(5) and 57 of the EPC. The 1977 Act brought about substantial changes to UK patent law, its stated purpose being to 'to establish a new law of patents' and 'to give effect to certain international conventions on patents'.<sup>44</sup> The Conventions mentioned are the EPC and the Community Patent Convention (*CPC*). The latter never came into force. Section 1 of the 1977 Act states:

---

<sup>42</sup> White, above n 2.

<sup>43</sup> Moufang, above n 3, 32-34.

<sup>44</sup> *Patents Act 1977* (UK), Recitals.

- (1) 'A patent may be granted for an invention in respect of which the following conditions are satisfied, that is to say-
- (a) the invention is new;
  - (b) it involves an inventive step;
  - (c) it is capable of industrial application;
  - (d) the grant of a patent for it is not excluded by subss (2) and (3) below;
- and references in this Act to a patentable invention shall be construed accordingly.'

S 4(1) and (2) then provides:

- (1) Subject to subs (2) below, an invention shall be taken to be capable of *industrial application* if it can be made or used in any kind of industry, including agriculture.
- (2) An invention of a *method of treatment of the human or animal body by surgery or therapy or of diagnosis practiced on the human or animal body shall not be taken to be capable of industrial application.*

(Emphasis added)

Although the 1977 Act uses different numbering from that of the corresponding provision of EPC and CPC,<sup>45</sup> it implemented those Conventions by using, in some parts, the same wording as their English language versions. In other places, however, the Act uses different language. For example the EPC refers to inventions that are 'susceptible of industrial application', whereas the 1977 Act refers to inventions that are 'capable of industrial application'. Nevertheless, it seems that the EPO and English courts adopted the same meaning to those phrases.

Section 4 of the 1977 Act clearly follows the terms of Art 52 of the EPC, excluding medical treatments from the definition of a patentable subject matter. In addition, as with the second sentence of Art 52(4), s 4(3) of the 1977 Act makes it clear that the prohibition in s 4(2) does not prevent a product consisting of a substance or composition being treated as capable of industrial application merely because it was invented for use in any such matter. Thus, s 4, as well as Art 52, second sentence, carefully distinguishes unpatentable methods of treatment from patentable medical products.

---

<sup>45</sup> EPC Article 177(1); CPC Article 102.



Since the criteria of patentability under the 1977 Act and the EPC do not differ, a high degree of consistency between decisions issued by the UK Patent Office, the English courts, and judgments delivered by the Boards of Appeal would be expected to be seen. For this reason, judgments from all of these jurisdictions are considered together below.

#### **2.4.1 Art 52(4), first sentence: surgery, therapy and diagnosis**

The legislatures have defined the contours of the field of medicine within the three separate categories of: 'surgery', 'therapy' and 'diagnosis'. It is important to emphasise that, for each category, the exclusion only applies to methods performed on a *living* animal or human body.<sup>46</sup> In principle, the three categories are independent. However, the categories share the same general requirement of having a medical character.<sup>47</sup> At the same time, the medical character of a method does not depend solely on the person who executes it. Hence, a method does not have a medical character simply because it is performed by a medical doctor rather than a non-medical practitioner or a nurse.

Before considering the case law on the exclusionary scope of these three categories in Art 52(4), it is useful to look at the Guidelines for Examination in the EPO (**Guidelines**). Although not binding upon the Boards of Appeal, the Guidelines provide useful parameters for defining the content and scope of excluded subject matter for the purposes of Art 52(4).

According to Guidelines C-IV, 4.3, first para, neither a treatment of body tissues or fluids after they have been removed from the human or animal body, nor a diagnostic method applied thereon are excluded from patentability. Similarly, storage in a blood bank or diagnostic testing of blood samples are not excluded. However, in cases involving treatment of blood by dialysis with the blood being returned to the same body, the treatment would be denied patentability. The UK Patent Office has adopted this approach following the decision of *Calmic Engineering*<sup>48</sup> of the UK Patents Court.

In the next paragraph, the Guidelines state that, regarding methods carried out on, or in relation to, the living human or animal body, it should be borne in mind that the intention of Art 52(4) is only to free from restraint non-commercial and non-industrial medical and veterinary activities. Interpretation of the provision should

---

<sup>46</sup> See, eg, Case t 182/90; *Guidelines for Examination*, C-IV, 4.3.

<sup>47</sup> Moufang, above n 3, 36.

<sup>48</sup> (1973) RPC 684. Note that this case was decided under the *Patents Act 1949* (UK).

avoid the exclusions going beyond their proper limits.<sup>49</sup> The Guidelines go on to give examples of surgery, therapy and diagnostic methods, referring to decisions of the Boards of Appeal, where appropriate.

#### 2.4.1.1 The field of surgery

Compared to extensive case law on the exclusion of therapeutic methods, discussed below, the exclusion of methods for treatment of the human or animal body by surgery have not yet been addressed extensively by the Boards of Appeal.

However, some points have been clarified in the case law.<sup>50</sup> For example, methods performed on corpses or actual extraction of organs from corpses do not fall under the exclusion clause of Art 52(4),<sup>51</sup> nor does the extraction of organs in transplants, which requires the use of an organ bank. This is because, from the meaning of the word 'surgery',<sup>52</sup> such operations would not be performed on a live body. However, were the extracted organ immediately implanted into a live body, it would fall within the scope of Art 52(4).<sup>53</sup>

According to Guidelines, surgery within the meaning of Art 52(4) defines the *nature* of the treatment rather than its purpose.<sup>54</sup> From the case law, the term surgery means the field of medicine involving the healing of diseases or accidental injuries, or remedies against physical defects by means of surgical operation or manipulation performed on a live body.<sup>55</sup>

Decision T 35/99<sup>56</sup> of the Board of Appeal states that the words 'methods for treatment of the human or animal body by surgery' mean: any (by its nature) surgical method, that can be carried out as such on the human or animal body. Consequently, a claim is not allowable under Art 52(4), first sentence, if it includes *at least one feature* defining a physical activity or action that constitutes a 'method for treatment of the human or animal body by surgery'; it is irrelevant whether the

<sup>49</sup> See decision G 5/83, OJ 3/1985, 64.

<sup>50</sup> See, eg, decisions in T 182/90 1994 OJ EPO, 641; T 35/99 2000 OJ EPO, Decisions of Technical Board of Appeal 3.2.2. dated 29 September 1999; T 820/92 1995 OJ EPO, 113; T 83/93 1996 OJ EPO, 274; *Unilever Ltd (Davis's) Application* 1983 RPC 219.

<sup>51</sup> See *Seymour v Osborn* (1870) 78 US 516, 533-34; *Kewanee Oil Co v Bicron* (1974) 416 US 470, 480-81; Moufang, above n 3, 36.

<sup>52</sup> See the definition of 'surgery' in the next paragraph.

<sup>53</sup> See Moufang, above n 3, 38.

<sup>54</sup> See C-IV, 4.3.

<sup>55</sup> See Cartegena Accord, Decision 344, *Common Regimen Patent to Industrial Property, Patents of Invention*, Article 6(f); *Implantieren von Haarbundeln* Decision of Federal Patent Court of December 12, 1988, 30 Bpat GE 134.

<sup>56</sup> T 35/99 2000 OJ EPO, Decisions of Technical Board of Appeal 3.2.2.

method in question is susceptible of being carried out in isolation, or in combination with other methods that together achieve the intended medical effect.<sup>57</sup>

From a UK perspective, surgery includes such operations as cutting the body, setting broken bones, and dental surgery.<sup>58</sup> Also, following a decision by the Patents Appeal Tribunal under the *Patents Act* 1949 (UK) in the case of *Oral Health Products (Halstead's) Application*,<sup>59</sup> methods of removing dental plaque, methods of cleaning teeth in which dental plaque is removed, and methods of treating human teeth with a fluorine-containing compound to prevent dental cavities, are to be refused as unpatentable by the UK Patent Office. On the other hand, procedures such as giving an injection, taking a blood sample, piercing ears, or tattooing are not regarded as 'surgery', the test applied being whether or not the skill or knowledge of a surgeon is required.<sup>60</sup>

Obiter remarks made by the Patents Court judge in *Unilever Ltd (Davis's) Application*<sup>61</sup> suggest that surgery can be curative of the disease or condition thereof, or prophylactic, that is, preventative of diseased conditions. For instance, the removal of an appendix or tonsils is a surgery even though a diseased condition did not yet exist. A surgery may be cosmetic without being curative or preventive. Therefore, it appears that in the UK view no form of surgery, whether it is curative, prophylactic or cosmetic, is patentable.<sup>62</sup> There is a high degree of consistency between UK Patent Courts' decisions and those issued by the Boards of Appeal.

In summary, the case law in relation to the exclusion of therapeutic methods, methods for treatment of the human or animal body by surgery indicates the following:

- the Art 52(4) exclusion affects only the surgical methods performed on a *living* body;
- the presence of a surgical step in a multi-step method of the treatment normally confers a surgical character on that method;

---

<sup>57</sup> T 35/99, point 8; T 82/93 1996 OJ EPO, 274; T 820/92 1995 OJ EPO 1995; T 182/90.

<sup>58</sup> KE Panchen, 'Patentability in the Field of Therapy and Diagnosis' (1991) 22 *International Review of Industrial Property & Copyright Law* 879.

<sup>59</sup> [1977] RPC 612.

<sup>60</sup> Panchen, above n 57, 880.

<sup>61</sup> [1983] RPC 219,220.

<sup>62</sup> Panchen, above n 57.

- as matter of policy, the terms 'treatment' and 'surgery' in Art 52(4) cannot be considered as constituting two distinct requirements for the exclusion provided therein;
- the exclusion encompasses *any* surgical activity, irrespective of whether it is carried out alone or in combination with other medical or non-medical measures;
- in the UK, no surgery whether it is curative, prophylactic or cosmetic, is patentable; and
- the UK view is not as broad as the EPO's and the exclusion of s 4(2) of the 1977 Act is not interpreted as one that encompasses *any* surgical activity.

#### **2.4.1.2 The field of therapy (prophylaxis and relief of pain)**

The second category excluded from patentability by Art 52(4), is the category of methods of therapeutic treatment. Here the exclusionary scope of Art 52(4) has been clearly outlined by the EPO decisions and national case law.

A dictionary meaning of the term 'therapy' refers to the medical treatment of disease. The first definition of the term was given in T 144/83.<sup>63</sup> According to this decision therapy relates to the treatment of a disease in general or to a curative treatment in the narrow sense as well as the alleviation of the symptoms of pain and suffering.

According to the EPO decisions, both prophylactic and curative treatments of disease have been held to come within the meaning of 'therapy' as used in Art 52(4).<sup>64</sup> Moreover, 'therapy' has been held to include the treatment of pain, discomfort and incapacity, regardless of origin.<sup>65</sup> For instance, in T 81/84, *Dysmenorrhea/Rorer*<sup>66</sup> the application was for the treatment of dysmenorrhea and one of the claims concerned a method for relieving discomfort of women during menstruation. The Board of Appeal considered that pain could stem both from illness and from natural causes. Such causes could overlap and were often indistinguishable. The Board of Appeal found that it was neither possible nor

---

<sup>63</sup> OJ 1986, 301.

<sup>64</sup> T 19/86, *PigsII/ Duphar*, 1989 OJ EPO, 24, point 7.

<sup>65</sup> T 81/84, *Dysmenorrhea/Rorer*, 1988 OJ EPO 207, 1988 GRUR Int 777, 19 *International Review of Industrial Property & Copyright Law* 803 (1988).

<sup>66</sup> 1988 OJ EPO 207, 1988 GRUR Int 777, 19 *International Review of Industrial Property & Copyright Law* 803 (1988).

desirable to distinguish between basic and symptomatic therapy, i.e. healing or cure, and mere relief. Therefore, the relief of pain, whatever its origin, was a 'therapy' within the meaning of Art 52(4).

Another example of broad interpretation of the term 'therapy' is found in the case T 116/85, *Pigs I/Wellcome*,<sup>67</sup> concerning pigs. In this case the Board of Appeal held that a treatment against parasites found on the human or animal body is very close to disease prevention, and it was not possible to distinguish a method applied by a farmer from the same method as applied by a veterinarian, and to say that the former, being an industrial activity, is patentable, whereas the latter is not.<sup>68</sup> The Board of Appeal made no distinction between treatments against transient and permanent ectoparasites, nor between ectoparasites and endoparasites. Consequently, the treatment at issue was held unpatentable.

As with surgery, both EPO and UK Patent Office practices have drawn a distinction between treatment carried out on the human or animal body and treatment carried out on a dead body. The latter is patentable, but the former is not.<sup>69</sup> From this approach, the inference could be drawn that a patent can be granted for treatments carried out on tissues and fluids removed from the body.<sup>70</sup> On this basis, treatment of blood by dialysis should also be patentable, as it would be possible to patent a treatment of the blood *itself* as it is removed from a patient.<sup>71</sup> Such an interpretation of the Art 52(4) would likely result in granting patents to inventions, which are currently excluded from patentability. However, the case law suggests that this approach is unlikely to prevail.<sup>72</sup> This provides clear authority for the proposition that treatments carried out on tissues and fluids removed from the body will not be granted a patent protection in Europe.

T 245/87 is an example where a medical competence of the practitioner may be an indication whether the method step is objectionable under Art 52(4) EPC. Claim 1 of the patent in issue in this case concerned a method by which an electrically conductive liquid containing a drug was introduced into the body through the pump of an implantable device for controlled drug administration. The method could be performed without involvement of a doctor.<sup>73</sup> The application was refused by the

---

<sup>67</sup> 1989 OJ EPO 13, 1989 GRUR Int 581, 20 *International Review of Industrial Property & Copyright Law* 188 (1989).

<sup>68</sup> *Pigs I/Wellcome*, 1989 OJ EPO 13, point 4.3.

<sup>69</sup> See the Guidelines C-IV, 4.3; *Calmac Engineering* (1973) RPC 684.

<sup>70</sup> Panchen, above n 57, 881.

<sup>71</sup> See the Guidelines C-IV, 4.3

<sup>72</sup> T 655/92 1998 OJ EPO, 17, points 5.2 and 5.3, head notes 2 and 3; T 329/94 1998 OJ EPO, 242, point 4.

T 964/99 2002 OJ EPO, 1, point 6.2.

<sup>73</sup> OJ 1989, 171

examining division on the basis of Art 52(4) EPC. The Board of Appeal held that the steps described in claim 1, even when applied to an implanted device for controlled drug administration, only involved measuring the volume of the drug solution flowing into the body. The flow itself was not affected. These steps could be performed without any medical knowledge and had no therapeutic effect. Based on these conclusions the Board of Appeal held that the method did not fall within the scope of Art 52(4) EPC, first sentence. The Board of Appeal also concluded that when there is no physical causality, between operations effected using a therapeutic apparatus and the therapeutic effect produced on the organism by that apparatus, a method will not be excluded under Art 52(4) EPC.

The key points of the case law regarding exclusion of methods of therapeutic treatment are listed below:

- the Art 52(4) exclusion affects only therapeutic treatment performed on a *living* body;
- both prophylactic and curative treatments of disease have been held to be within the meaning of 'therapy';
- 'therapy' has been held to include the treatment of pain, discomfort and incapacity, regardless of origin;
- it is not possible to draw a distinction between a method applied by a farmer and the same method as applied by a veterinarian and to say that the former, being an industrial activity, is patentable, but the latter is not;
- the treatment of blood by dialysis will be excluded;
- methods will be susceptible of industrial application if they could be used with the desired result *by a technician* without specialist medical knowledge and skills;<sup>74</sup>
- a method will not be within the scope of Art 52(4) EPC when there is no physical connection between operations effected using a therapeutic apparatus and the therapeutic effect produced on the organism by that apparatus;<sup>75</sup> and

---

<sup>74</sup> Ibid.

<sup>75</sup> Ibid.

- Prophylactic treatment<sup>76</sup> and method for preventing pregnancy<sup>77</sup> might amount to a 'therapy'.

#### 2.4.1.3 The field of diagnosis

Art 52(4) also excludes methods of diagnosis. Generally, the term 'diagnosis' refers to examination leading to the identification and treatment of disease. Diagnosis may also be performed on a body for the determination and maintenance of health.

A few difficulties have arisen with regard to this interpretation of the methods of diagnosis exclusion. The exclusionary scope of Art 52(4) covers only methods of diagnosis that are carried out on a living human or animal body. Thus, according to the prevailing opinion of the EPO decisions and national case law, diagnostic methods performed on tissues, organs or fluids permanently removed from the body may not be subject to the exclusionary scope of the Art 52(4).<sup>78</sup> However, more recent decisions of the Boards of Appeal suggest that this is not always so.<sup>79</sup> On the basis that diagnosis leads to disease identification, the UK Patent Office has adopted the following tests:

1. does the method, unaided by other tests, indicate whether or not a person or animal is suffering from a medical disorder; and
2. does the method identify the disorder where it is found to be present?<sup>80</sup>

In the event of an affirmative answer to both of these questions, the method in question will be regarded as a method of diagnosis practiced on the human or animal body, and therefore excluded by the 1977 Act.

According to the Guidelines, Part C-IV, 4.3, methods for obtaining information from the living human or animal body are not excluded by Art 52(4) if the information obtained merely provides intermediate results. This is because methods providing only interim results do not, on their own, enable a decision to be made on the treatment. They merely aid an eventual diagnosis. Thus, methods using nuclear magnetic resonance to obtain measurements (such as temperature and pH),<sup>81</sup> or X-

<sup>76</sup> G 5/83, 1985 OJ EPO 64.

<sup>77</sup> T 820/92, 1995 OJ EPO, 113.

<sup>78</sup> Bernard & Kraber, *Lehrbuch des Patentrechts*, (4<sup>th</sup> ed., Munich, 1986), 129; Panchen, above n 57, 885; Moufang, above n 3, 45.

<sup>79</sup> T655/92, 1998 OJ EPO; T 329/ 94, 1998 OJ EPO; T 964/99, 2002 OJ EPO.

<sup>80</sup> Panchen, above n 57, 886.

<sup>81</sup> *Diagnostizierverfahren*, 1985 GRUR 278 (German Fed. Pat. Ct.).

ray investigations and blood pressure measurements<sup>82</sup> do not, generally, comprise a method of diagnosis.

The Board of Appeal in T 385/86, *Non-Invasive Measurement/Bruker*,<sup>83</sup> having considered the historical origins of the exclusion made by the Art 52(4), held that its exclusionary scope covers only methods of diagnosis that:

- are carried out on a *living* human or animal body;<sup>84</sup>
- include examinations whose *results immediately make it possible* to decide on a particular course of medical treatment;<sup>85</sup>
- contain *all the steps* involved in reaching a medical diagnosis.

Thus, according to the Boards of Appeal, methods providing only interim results are not diagnostic methods in the meaning of Art 52(4), first sentence, even if they can be utilised in making a diagnosis. This decision had been widely accepted and confirmed in subsequent decisions.<sup>86</sup>

However, in T 964/99, *Cycnus Inc*<sup>87</sup> the Board of Appeal expressed the opinion that a strict adoption of the above principles would lead to the conclusion that typical diagnostic procedures practised on the human body, like percussion, auscultation or palpation could, in principle, be patentable. This would be the case because they do not constitute a complete diagnosis (as they do not contain *all the steps* involved in reaching a medical diagnosis) and do not fall within the categories of 'surgery' and 'therapy' referred to in Art 52(4). The Board of Appeal considered that this approach would go against the spirit of Art 52(4).<sup>88</sup>

It follows that the Boards of Appeal are of the opinion that Art 52(4) is meant to exclude from patent protection all methods practised on the human or animal body *that relate to* diagnosis or which are of *value for* the purpose of diagnosis. This meaning of 'diagnostic methods' adopted by the Boards of Appeal come from the

---

<sup>82</sup> T 61/83, Dated 21 November 1983, not published in the OJ EPO; T 385/86 *Non-Invasive Measurement/Bruker*, T 385/86, 1988 OJ EPO 308, 1988 GRUR Int 938, (1989) 20 *International Review of Industrial Property & Copyright Law* 75.

<sup>83</sup> T 385/86, *Non-Invasive Measurement/Bruker*, 1988 OJ EPO 308, 1988 GRUR Int 938, (1989) 20 *International Review of Industrial Property & Copyright Law* 75.

<sup>84</sup> T 385/86, *Non-Invasive Measurement/Bruker* point 3.2.

<sup>85</sup> *Ibid.*

<sup>86</sup> T 83/87, T 400/87 and T 530/93 (Not published in OJ EPO).

<sup>87</sup> 2002 OJ EPO.

<sup>88</sup> T 964/99, *Cycnus Inc* 2002 OJ EPO, point 3.5.



strict interpretation of the terms 'diagnosis' and 'diagnostic' in the Oxford English Dictionary.<sup>89</sup> Hence, the straightforward meaning of 'diagnostic methods' would be 'methods pertaining to, or of value for the purposes of, diagnosis'.<sup>90</sup> By employing this meaning, it would appear that any medical activity concerning the gathering of information in the course of establishing a diagnosis qualifies as a diagnostic method.

In summary, the case law on exclusion of methods of diagnosis indicates the following:

- the exclusionary scope of Art 52(4) covers only methods of diagnosis that are carried out on a *living* body;
- methods for obtaining information from the living human or animal body are not excluded by Art 52(4) if the information obtained merely provides intermediate results;
- methods of diagnosis will be excluded where their results immediately make it possible to decide on a particular course of medical treatment and contain *all the steps* involved in reaching a medical diagnosis;
- with regard to exception to patentability, Art 52(4) must be construed narrowly;
- methods will be susceptible of industrial application if they could be used with the desired result *by a technician* without specialist medical knowledge and skills; and
- Art 52(4) is meant to exclude from patent protection all methods practiced on the human or animal body which relate to diagnosis or which are of value for the purpose of diagnosis.

#### **2.4.2 Cosmetic products and therapeutic treatments**

In principle, cosmetic methods are not included in the category of therapeutic methods, because cosmetic treatment is interpreted by the Boards of Appeal as a method designed or intended to improve appearance of the human body.<sup>91</sup>

---

<sup>89</sup> Second Edition, Oxford University Press, 1999.

<sup>90</sup> T 964/99, *Cycnus Inc* 2002 OJ EPO, I, point 4.2.

<sup>91</sup> T 290/86 (OJ 1992, 414); T 144/83 (OJ 1986, 301) T 36/83 (OJ 1986, 295).

'Therapy', on the other hand, as discussed earlier, clearly relates to medical treatment of disease, and includes both prophylactic and curative treatments of disease in the narrow sense,<sup>92</sup> as well as the treatment of pain, discomfort and incapacity, regardless of origin.<sup>93</sup>

However, the cases involving cosmetic product claims are not always clear-cut. A complex situation arises when a method of treatment displays *both* a therapeutic and cosmetic effect. The EPO Technical Board of Appeal (the **Technical Board**) has generally favored the proposition that in the case where a non-therapeutic effect can be distinguished from a therapeutic one, a claim only to the therapeutic effect is excluded from patent protection.<sup>94</sup>

In T 144/83, *Appetite Suppressant/Du Pont*<sup>95</sup>, for example, the Technical Board admitted that no core distinction could be drawn between the cosmetic treatment in question for improving the bodily appearance and the medical treatment for curing obesity. The Technical Board's view was that the fact that a chemical had both a cosmetic and therapeutic effect did not render the cosmetic treatment unpatentable. The Technical Board held that Art 52(4) must be construed narrowly so as not to work to the disadvantage of an applicant seeking patent protection for the cosmetic treatment only. The decision has since been criticized by commentators<sup>96</sup> and distinguished by later decisions.<sup>97</sup>

Although there was no clear distinction between the therapeutic and the cosmetic effect, the Technical Board allowed the method for cosmetic treatment. It is submitted that it would be wrong to view this case as authority for the propositions that if there is any doubt as to whether the prohibition of Art 52(4) applies it must be resolved in the applicant's favour, or that something described as a 'cosmetic' treatment can *ipso facto* be construed as non-therapeutic.<sup>98</sup> This is because a 'cosmetic' treatment might have therapeutic as well as cosmetic effect and therefore, treated as method of medical treatment of disease.

---

<sup>92</sup> T 19/86, *PigsII/Duphar*, 1989 OJ EPO, 24, point 7.

<sup>93</sup> T 81/84, *Dysmenorrhea/Rorer*, 1988 OJ EPO 207, 1988 GRUR Int 777, 19 *International Review of Industrial Property & Copyright Law* 803.

<sup>94</sup> T 144/83, 1986 OJ EPO, 301, point 4.

<sup>95</sup> T 144/83 *Appetite Suppressant/Du Pont*, 1986 OJ EPO 301, 1986 GRUR Int 720, (1987) 18 *International Review of Industrial Property & Copyright Law* 258.

<sup>96</sup> Panchen, above n 57; Moufang, above n 3; Todd Martin, 'Patentability of Methods of Medical Treatment: A Comparative Study' (2000) 82 *Journal Of The Patent And Trademark Office Society* 381.

<sup>97</sup> T 290/86, 1992 OJ EPO 414; T 820/92 1995 OJ EPO 113.

<sup>98</sup> 36/83 *Thenoyl Peroxide/Roussel-Uclaf*, 1986 OJ EPO 295, 1986 GRUR Int 717. See also T 582/88 Unreported, cited in the 1990 case law report, 1991 OJ EPO 19 and 290/86 1992 OJ EPO 414.

The cases involving cosmetic product and/or treatment claims indicate that:

- where a non-therapeutic effect can be distinguished from a therapeutic one, a claim only to the non-therapeutic effect is not excluded from patent protection; and
- where a treatment has overlapping and therefore indistinguishable effects, which are inextricably linked with therapy, a claim for anything other than a second medical use is excluded from patentability.

#### **2.4.3 Conclusions on the case law relating to the interpretation of Art 52(4)**

From this line of EPO and UK decisions it follows that 'pure' surgical, therapeutic and diagnostic methods are excluded by Art 52(4). In considering whether a request is allowable under Art 52(4), the critical questions are whether it is going to be performed on a *living* body and whether the claimed steps involve either a method for the treatment of the human or animal by therapy or surgery.

With methods of diagnosis, it has been suggested that a strict interpretation of the T 385/86 *Non-Invasive Measurement/Bruker* case,<sup>99</sup> results in the practical dissolution of the legislative exclusion of diagnostic methods.<sup>100</sup> However, the later EPO cases did not consider the reason in T 385/86 *Non-Invasive Measurement/Bruker* as a good law, and adopted significantly broader approach, which would make it even more difficult to obtain a patent protection for methods that provide only interim results.

When a method of treatment displays both a therapeutic and cosmetic effect, the methods that have agents or compounds that demonstrate *different properties*, rather than *different effects*, are more likely to obtain the patent protection.

---

<sup>99</sup> The strict interpretation is that Article 52(4) EPC covers only methods of diagnosis whose *results immediately make it possible* to decide on a particular course of medical treatment, and thus, methods providing only interim results are not diagnostic methods in the meaning of Article 52(4): T 385/86, *Non-Invasive Measurement/Bruker* point 3.2.

<sup>100</sup> Moufang, above n 3.

## 2.5 SWISS-TYPE CLAIMS UNDER ART 54(5) EPC

From the above discussion of the exclusionary scope of Art 52(4) it is clear that claims directed to methods of treatment are excluded from patentability. However, claims directed to the 'use of compound X in the manufacture of a medicament for a new therapeutic use' fall outside of the exclusion. These claims, called 'Swiss-type claims', are also referred to as 'second medical use'.

Swiss-type claims are named after the practice adopted by the Swiss Office of Intellectual Property, which allows patents for the use of compounds for therapeutic treatment when worded as follows: 'Use of a compound...for the *manufacture* of means intended to treat the disorder...' Claims of this nature have been developed as a result of the interpretation of Art 54(5) and the pharmaceutical industry's pressure to provide protection for second and further medical uses. It has been argued by the pharmaceutical manufacturers and their representative organizations that patent protection operates as an incentive to engage in research for new pharmaceutical uses of known substances, and is needed to enable recovery of the research and development expenditure.<sup>101</sup> It is submitted that these same arguments could be equally raised against exclusions of methods of treatment of the human body by surgery or therapy and diagnosis in Article 52(4).

Art 54(5) states:

1. An invention shall be considered to be new if it does not form part of the state of the art.
2. The state of the art shall be held to compose everything made available to the public by means of a written or oral description, by use or in any other way, before the date of filing of the patent application.
- ...
5. The provisions of paragraphs 1 to 4 shall not exclude the patentability of any substance or composition, comprised in the state of the art, for use in a method referred to in Art 52, paragraph 4, provided that its use for any method referred to in that paragraph is not comprised in the state of the art.

---

<sup>101</sup> *Eisai/Second Medical Indication* (1985) OJ EPO 60; *John Wyeth & Brother Ltd's Application* and *Schering A.G's Application* [1985] RPC 545.

### 2.5.1 First Therapeutic Use

The exclusion of patents for methods of treatment of the human body by surgery or therapy and diagnosis created problems for inventors who discovered that a known substance, used in a field of human activity completely unrelated to medicine, has a medical use; for example, the first use of silicone rubber as an implant in cosmetic surgery.<sup>102</sup> Since the compound is known, it would not meet the requirement of novelty under patent legislation, and so it would not be possible to obtain patent protection for the substance *per se*.

Although, according to Art 54(1), the law denies novelty to a substance if it does not go beyond the state of the art, Art 54(5) creates an exception for a substance for use in a method referred in Art 52(4). Thus, the wording of Art 54(5) is taken to imply an authorization for patent protection for the first therapeutic use of a substance even when there is no novelty in the substance itself.<sup>103</sup>

### 2.5.2 Second Therapeutic Use

Further problems arise when a drug is already known for one or more therapeutic applications, and another, unexpected discovery has been made about the curative properties of that drug. To understand the problem, consider the example of the use of aspirin. It is well known that aspirin is used for its anti-inflammatory property in treating humans. Take a newly discovered use for aspirin, namely its use in prophylaxis of strokes. There is no novelty in the substance since the drug is already known. The first therapeutic use is also known. The question arises: 'Can a newly discovered second use for aspirin be patentable?'

The difficulty is that such new manner of use is directed to treat a disease in human beings, and is thus a method of therapeutic treatment, which is excluded under Art 52(4) as not being susceptible of industrial application. Can the discovery of a new pharmaceutical use be protected in such a way as to leave the medical practitioner unrestrained, and at the same time remain outside of the exclusionary scope of Art 52(4)? The Swiss-type claim serves as the means of achieving such protection. In order to understand how such a new pharmaceutical use claim may circumvent the exclusionary scope of Art 52(4), it is necessary to review the case law of the Members States of the EPC and the Boards of Appeal of the EPO.

---

<sup>102</sup> Panchen, above n 57, 883.

<sup>103</sup> *Commissioner of Patents v Wellcome Foundation Ltd* (1983) 2 IPR 156, 163 (Somers J).

### 2.5.2.1 Germany: *Hydropyridine*<sup>104</sup>

In Germany, in the *Hydropyridine* case the Federal Supreme Court allowed a claim for the *use* of a compound to treat cerebral insufficiency, even though it was already known as a drug for treating coronary disorders. The court took the view that a claim to the use of a substance to treat an illness extended beyond the giving of the substance to a patient, and included the preparation or formulation of the substance for use in treating the illness by therapy.<sup>105</sup> The court concluded that although s 5(2) of the German *Patents Act* is worded identically to Art 52(4), it does not exclude from patentability an invention involving the *use* of a known substance to treat illness.

### 2.5.2.2 The European Patent Office: *Eisai*<sup>106</sup>

The approach in *Hydropyridine* differed fundamentally from the view taken by the Boards of Appeal and the UK Patents Court, created a problem of harmonisation. For example, in case *Re Eisai Co. Ltd* (Decision Gr 05/83)<sup>107</sup> (*Eisai*) the Board of Appeal said:

... it is therefore difficult for the Patent Office to follow the practice of a superior court of only a single Contracting State in a matter which has a bearing on questions of infringement...however eminent that court may be.<sup>108</sup>

In *Eisai* the Board of Appeal said that 'a claim directed to the use of a substance or composition for the treatment of the human or animal body by therapy is to be regarded by the European Patent Office as confined to the step of treatment',<sup>109</sup> and it therefore prohibited by Art 52(4). The Board then considered the possibility of protecting a second medical use claim according to the practice followed by the Swiss Office of Intellectual Property of allowing claims for uses of compounds for therapeutic treatment, described above. According to the Board of Appeal, the novelty of such applications resided in the new therapeutic use, and since the claim was to the manufacture of the substance, it was not a claim to a method of treatment.

---

<sup>104</sup> BGH 20 September 1983; 1983 GRUR 729; (1984) OJ EPO 26.

<sup>105</sup> *Hydropyridine* (1984) OJ EPO 26, 28 para 2.

<sup>106</sup> *Eisai/Second Medical Indication* (1985) OJ EPO 60.

<sup>107</sup> *Ibid.*

<sup>108</sup> *Ibid.*, point 18.

<sup>109</sup> *Ibid.*

The interpretation of Art 54(5) was one of the main issues discussed in the judgment in *Eisai*. The Board of Appeal stated that an exception was provided in so far as the first use of a substance is concerned. Thus, in the first use claim the novelty derived from the new pharmaceutical use. It found that it would be justifiable 'by analogy' to derive the novelty for the process from the newly discovered therapeutic use of the medicament irrespective of whether or not any pharmaceutical use of the medicament was already known.<sup>110</sup>

The Board of Appeal held that it was legitimate in principle to allow claims directed to the use of a substance or composition for the manufacture of a medicament for a specified new and inventive therapeutic application, even in a case where the process of manufacture as such does not differ from known processes using the same active ingredient.

### 2.5.2.3 The United Kingdom: *Wyeth* and *Schering*<sup>111</sup>

The reasoning in *Eisai* has since been the subject of considerable discussion amongst patent lawyers. In 1985, the UK Patents Court sitting *en banc* (Whitford and Falconer JJ) in the *Wyeth* and *Schering* cases recognized the importance of *Eisai* and held that this case must be followed in the UK. The Court accepted claims to an invention directed to the use of a substance X to obtain a drug for a new therapy and involving an inventive step.

The Court confirmed that the approach of the Boards of Appeal to the novelty of the Swiss-type claim directed to a second and subsequent therapeutic use is equally possible under the corresponding provisions of the 1977 Act and should be adopted. However, it is worth noting that even though the Court formed the view that a Swiss-type claim was clearly a claim to method of manufacture and an invention capable of industrial application, it stated that it was the requirement of novelty that 'provides the real difficulty'. The Court expressed the view that the device of putting a claim into Swiss-form did not confer novelty:

...we think the better view would be that a claim in the Swiss form to an invention directed to the use of a known pharmaceutical to manufacture a medicament, not in itself novel, for a second or subsequent and novel medical use *would not be patentable as lacking the required novelty*.<sup>112</sup>

---

<sup>110</sup> Ibid, 66.

<sup>111</sup> *John Wyeth & Brother Ltd's Application* and *Schering A.G's Application* [1985] RPC 545.

<sup>112</sup> Ibid, 565 (*Emphasis added*).

However, 'having regard to the desirability of achieving conformity' the Court decided not to follow what it regarded as the better view, but rather, it decided to follow *Eisai*.<sup>113</sup>

#### 2.5.2.4 Sweden and Netherlands

In 1986, the Swedish Court of Patent Appeals in *Patentbesvarsrätten*<sup>114</sup> followed the decision on the Enlarged Board in the *Hydropyridine/SE* case<sup>115</sup> and stated that the patentability of the Swiss-type claim directed to a second or subsequent medical use was accepted in Sweden prior to her membership in the EPC.

In 1987 the Netherlands Patent Office Appeal Division in *Octooiraad*<sup>116</sup> rejected the criterion of novelty in *Eisai*. The Appeal Division in this case took the view that novelty did not derive from the mere fact that the known compound had a new therapeutic use. However, the wording of the Netherlands legislation differs from that of the EPC and this justified the different approach as regards patentability of the Swiss-type claims taken by the Appeal Division. It appears therefore, that interpretation of Art 54(5) was not involved.

#### 2.5.3 Criticism of Swiss-Type Claims

Taking into account the cases discussed, the following points can be made on the patentability of the Swiss-type claims:

- a European patent cannot be granted to a claim directed to a newly discovered second use of the substance as it is viewed as being a therapeutic treatment of the human or animal body;
- a European patent can be granted to a claim directed to the use of a compound for the manufacture of a medicament intended for a specified new and inventive therapeutic treatment; and
- the novelty of the medicament claimed may derive from the novelty of the new therapeutic application, whether or not it is first.

---

<sup>113</sup> *Bristol-Myers Squibb Co v Baker Norton Pharmaceuticals Inc* [1999] RPC 253, 255 (Jacob J).

<sup>114</sup> Commented by Pierre Lancon, 'Patentability in the Field of Therapy and Diagnosis' (1991) 22 *International Review of Industrial Property & Copyright Law* 893, 900.

<sup>115</sup> 1988 OJ EPO 198, 1988 GRUR Int 788, (1988) 19 *International Review of Industrial Property & Copyright Law* 815.

<sup>116</sup> 1988 OJ EPO 405, 1989 GRUR Int 588, (1989) 20 *International Review of Industrial Property & Copyright Law* 220.



The English case of *Bristol-Myers Squibb Co v Baker Norton Pharmaceuticals Inc*<sup>117</sup> is an example where a claim drafted in the Swiss-type form may nevertheless not secure patent protection. In this case the claim for invention arising from the discovery of new efficacy of a known anti-cancer chemical was drafted as follows: 'Use of taxol for the manufacture of a medicament for the treatment of cancer.'

Jacob J, in considering the validity of this Swiss-type claim, expressed reluctance in following the *Eisai* decision. His Honour found the patent invalid for want of novelty and obviousness on the ground that it was not a case of second and new medical use but simply involved discovery and disclosure of more information about a known use. Jacob J expressed his concern about the problems the Swiss-type claims create and said:

In my view it is essential for the granting authority to consider fully the *implications* of the claims it grants in relation to both validity and scope. It is not helpful to take a view on validity (particularly novelty) which simply leaves intractable problems for an infringement court- and for the public who need to know what they can and cannot do.<sup>118</sup>

Jacob J proceeded to comment on the *Eisai* decision:

There are obvious difficulties with *Eisai*. Take a newly discovered use for aspirin (one was discovered not so long ago, namely its use to reduce risks of heart attacks). The manufacture of aspirin pills is old. So why is the manufacture rendered new because there is a new use? Or why does adding the purpose of the manufacture of aspirin to the claim make the manufacturing process any newer?<sup>119</sup>

As a judge of first instance, however, Jacob J did not go against *Eisai* as this would have involved not only refusing to follow a decision of law made by the Boards of Appeal, but refusing to follow the considered judgments of the English Patents Court in *Wyeth* and *Schering*. In highlighting his inability to declare such authorities 'bad law'<sup>120</sup>, Jacob J was clearly looking for another reason for refusing a second medical use patent.<sup>121</sup> Ultimately, his Honour followed *Wyeth* and *Schering*, and

---

<sup>117</sup> [1999] RPC 253.

<sup>118</sup> *Bristol-Myers Squibb Co v Baker Norton Pharmaceuticals Inc* [1999] RPC 253, 272.

<sup>119</sup> *Ibid.*

<sup>120</sup> *Ibid.*, 277.

<sup>121</sup> See *John Wyeth & Brother Ltd's Application* and *Schering A.G's Application* [1985] RPC 545, 565; *Bristol-Myers Squibb Co v Baker Norton Pharmaceuticals Inc* [1999] RPC 253, 272. Jacob J's ground for

accepted that novelty may rest on disclosure for the first time of a newly discovered technical effect even though a method of treatment could not be claimed.

Jacob J added that the thinking behind the exclusion from patentability of methods of medical treatment was 'not particularly rational'.<sup>122</sup> He pointed out that in the US any such exception has been removed and so far this removal has caused no trouble to the physician's freedom of treatment.

## 2.6 INVENTIONS CONTRARY TO 'ORDRE PUBLIC' OR MORALITY

The technical criteria in Art 52(4) EPC should be read in conjunction with the exclusionary provisions of Art 53 EPC. Art 53 defines the exceptions to patentability as follows:

(a) inventions the publication or exploitation of which would be contrary to '*ordre public*' or *morality*, provided that the exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation in some or all of the Contracting States; and

.....

The necessity to protect social values and public interest has a long-established tradition in patent law. It goes back to the early cases of the Tudor period that led to the enactment of the 1624 *Statute of Monopolies*. Although the origins of the *Statute of Monopolies* and the meaning of the proviso to s 6 will be discussed in detail in Chapter 5, for the purpose of the present discussion it is necessary to note that *Statute of Monopolies* made all monopolies void, except those that the *Statute* recognised itself. Section 6 of the *Statute of Monopolies* expressly limits the ambit of patentable subject matter and treats inventions void when they are *contrary to the law, mischievous to the State, to the hurt of trade or generally inconvenient*.

According to Hindmarch, the phrase '[the patent grant] *must not be contrary to law*' refers to common law as well as the patent statute itself so as one law cannot grant patents that serve as a reward to persons for providing the means of violating any other law.<sup>123</sup> As it will be revealed from the discussion in Chapter 5, the meaning of the term '*generally inconvenient*', however, is far from clear as it is incapable of being translated by literal statutory interpretation.

---

refusal was that it was not a case of a second or other medical use, but rather a case of a mere discovery about an old use.

<sup>122</sup> *Bristol-Myers Squibb Co v Baker Norton Pharmaceuticals Inc* [1999] RPC 253, 272.

<sup>123</sup> W M Hindmarch, *A Treatise on the law relating to patent privileges for the sole use of inventions* (1846), 142.

Notwithstanding the ambiguity of some terms of s 6, it is said that '[Section 6] established as a rule that all prerogatives must be for the advantage and good of the people, otherwise they ought not to be allowed by the law'.<sup>124</sup> It would appear, therefore, that public good was always intended to be part of the patent system, right from its origins in the *Statute of Monopolies*. Consequently, in the Guidelines and Directive of the EPC, ethical and moral principles are acknowledged as being supplemental to the legal requirements under patent law irrespective of the particular technical field under examination.<sup>125</sup>

The term '*ordre public*' is a French term, which cannot be readily translated into English. For this reason the original French term is used in Art 53 (a) as well as in Art 27.2 of the Agreement on Trade-related Aspects of Intellectual Property Rights 1995 (*TRIPS*).<sup>126</sup>

Since '*ordre public*' is retained in original French words, one would argue that it cannot be translated into 'public order' directly. However, this is what the Guidelines effectively indicate. Thus Part C-IV, 3.1 provide that the purpose of Art 53 (a) is to 'exclude from protection inventions likely to induce riot or public disorder, or to lead to criminal or other generally offensive behaviour'. This seems to indicate that the Guidelines identify '*ordre public*' as akin to the English concept of public order. Similarly, s 1(3)(a) of the Patents Act 1977 (UK) provides that a patent shall not be granted 'for an invention the publication or exploitation of which would be generally expected to encourage offensive, immoral, or anti-social behaviour'.

In respect of interpretation of '*ordre public*' by the Boards of Appeal, the case law indicates that any exceptions to patentability must be narrowly construed.<sup>127</sup> T 19/90 was the first decision to deal with ethical issues under Art 53(a). This case concerned a transgenic non-human mammalian animal whose germ cells and somatic cells contain in the genome an activated oncogene which increases the

<sup>124</sup> M A Bacon, *New Abridgement of the law*, (7<sup>th</sup> ed, 1832 ) volVI, 384.

<sup>125</sup> See, eg European Commissions, Council Directive, *On The Legal Protection of Biotechnological Inventions* (1998) [44] (The Directive); The Directive provides a list of specific exclusions as well as a general provision regarding application of Art 53(a) EPC. By virtue of the Directive examples of inventions are given to provide national courts and patent offices with a general guide to interpreting the reference to *ordre public* and morality in Art 53(a).

<sup>126</sup> See Article 27.2 of the TRIPS Agreement, which provides that Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect *ordre public* or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law.

<sup>127</sup> T 356/93 (OJ 1995, 545).

probability of neoplasm development in the animal, and a method for producing such an animal. According to the Boards of Appeal, before deciding whether to grant or refuse the patent application, an examining division had to carefully weigh up of the suffering of animals and possible risks to the environment on the one hand, and the usefulness of the invention on the other.<sup>128</sup> After remitting of the case to the examining division by the Boards of Appeal, the patent was granted.

Since this decision, amendments to the Implementing Regulations of the EPC give guidance on the definition of certain terms, providing that the relevant provisions of the EPC shall be applied and interpreted in accordance with the provisions of these rules, as amended. New R 23d EPC provides that patents shall not be granted in respect of biotechnological inventions which *inter alia* concern processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal, and also animals resulting from such processes.

Another case that considered the issue of morality was T 356/93.<sup>129</sup> The invention concerned a method that promotes resistance in plants and seeds to a particular class of herbicides so that they could be selectively protected against weeds and fungal diseases. The method involved integration into the genome of the plants a heterologous DNA encoding a protein capable of inactivating or neutralising the herbicides. The patent was opposed under Art 53(a) EPC on the grounds that the exploitation of the invention was likely to cause serious damage to the environment. The Boards of Appeal emphasized that even though it might be difficult to judge whether or not a claimed subject matter was contrary to '*ordre public*' or morality, the provisions of Art 53(a) EPC could not be disregarded. Each case had to be considered in accordance with its circumstances.

The Boards of Appeal interpreted the concept of '*ordre public*' as covering the protection of public security and the physical integrity of individuals as part of society. It also included the protection of the environment.<sup>130</sup> Accordingly, inventions, the exploitation of which was likely to seriously prejudice public security and/or the environment, were to be excluded from patentability as being contrary to '*ordre public*'.

In relation the concept of morality, the Boards of Appeal commented that it related to the belief that while some behavior was acceptable, other behavior was not. This

---

<sup>128</sup> OJ 1992, 588.

<sup>129</sup> OJ 1995, 545.

<sup>130</sup> Ibid.

belief was founded on the totality of the accepted norms and deeply rooted in a particular culture. For the purposes of the EPC, the culture in question was the culture inherent in European society and civilisation. It followed, therefore, that those inventions the exploitation of which was not in conformity with the conventionally accepted standards of conduct adopted by this culture were to be excluded from patentability as being contrary to morality.

In this case the Board of Appeal ruled that, although there were chances of possible hazards from the application of genetic engineering techniques to plants, they did not lead to the conclusion that the exploitation of any of the claimed subject-matter would seriously prejudice the environment. Consequently, Art 53(a) EPC did not constitute a bar to patentability of the invention.

Accordingly, an invention will be excluded from patentability under Art 53(a) if it raises serious social and ethical concerns. The discussion of the UK case law in Chapter 1 revealed that for the last 30 years the exclusion of methods of medical treatment from patenting is based on public policy and ethical grounds. It could be argued therefore that if methods of medical treatments should be excluded under European patent law, the exclusion should be made under Art 53(a). On the other hand, given that Art 53(a) has been narrowly applied,<sup>131</sup> it will be invoked in extreme cases, where an invention is likely to seriously induce public disorder or lead to criminal offences and/or endanger the environment. Since methods of medical treatment bring potential relief to numerous sufferers, can their patents be viewed to be contrary to the *ordre public* and morality? Based on current interpretation of Art 53(a), it is unlikely.

Yet, as it will be demonstrated by discussion in Chapters 5 and 6, the scope of any term in legislation, is a matter of interpretation. It is submitted, therefore, that instead of express prohibition of patents to methods of medical treatment, each patent application must be reviewed against the '*ordre public*' and morality exclusion. Each case should be considered in accordance with its circumstances.

---

<sup>131</sup> T 356/93 (OJ 1995, 545).

## 2.7 CONCLUSION

A long history of the prohibition of methods of medical treatments in the UK and other European countries led to the enactment of Art 52(4) of the EPC, which expressly excludes 'methods of medical treatment of the human or animal body by surgery or therapy and diagnostic methods practiced on the human or animal body' from patentability by treating them as not 'susceptible of industrial application'.

The interpretation of the wording of Art 52(4) 'shall not be regarded as' seems to suggest that such methods would in fact be susceptible of industrial application but for that prohibition. Therefore, though with some reservations, it is an artificially created state of affairs to disallow patentability of methods of medical treatment.

With the introduction of the Swiss-type claims format, Art 52(4) is left with no scope for exclusion of methods of medical treatment involving second therapeutic applications. Accordingly, the effect of the acceptance of the Swiss-type claims by the EPO Board is to emasculate the methods of medical treatment exclusion contained in Art 52(4) and, thus, allow patenting of such methods when they involve the use of a substance.

### **Hypothetical Example: Procedure For The Preparation Of A Donor Bone Marrow Transplant**

To form a clear picture of the implications of the law related to the patentability of methods of medical treatment, consider a hypothetical physician who invented and patented a cure for a current unsolved problem with so-called graft-versus-host disease, which makes a bone marrow transplant procedure hopeless for many leukemia patients. This disease is an immune reaction of the donor bone marrow against the recipient tissues. In other words, the donor bone marrow does not take properly in the recipient's body, and attacks the recipient's tissues instead.

Essentially, our hypothetical physician has invented a method for the preparation of donor bone marrow. This preparation has the effect of decreasing the immune reaction against the recipient's tissues so that the donor bone marrow 'takes' well. Under UK and EPC law, that physician may or may not be able to patent this invention. The result depends upon the format used for the patent application.

- *'The method for...'* format

Assume the hypothetical physician wishes to obtain a patent for the pure 'method for the preparation of a donor bone marrow'. Under UK and the EPC law, he may not be able to patent this invention. This claim would fall into the narrow view of the term of 'medical treatment', since its performance requires the use of professional medical knowledge and skill.

- *'The use of a device' format*

Assume the hypothetical physician has invented a new device that can be used for preparation of bone marrow. By making general patent claim for 'the use of a device' and omitting the step of performing a medical procedure, he would be able to obtain patent protection for this invention.

- *'The new use of a known drug X' format*

Suppose the hypothetical physician discovers that an already known drug X can be used in a *new* way to suppress the immune system to allow donor bone marrow to 'take' well. Under UK and the EPC law, the physician can patent the new use of the *drug X*, using Swiss-type claiming, provided that claim is not seeking patent protection for administering this drug.

- *'The procedure, using the drug X' format*

Suppose that the hypothetical physician discovers that drug X, when used as described in the patent specification, in combination with a surgical procedure invented by her, substantially decreases the graft-versus-host disease. If the physician chooses to obtain a patent on the procedure, using the drug X, it is likely that the patent would not be allowed, since it would be treated as a 'pure' method of medical treatment claim.

### **Summary of key findings**

It follows from the above example that only 'pure' surgical, therapeutic and diagnostic methods are excluded from patent protection in Europe, which in practice makes the exclusion of minimum value. The justification for this conclusion is that, with possibility of securing patent protection via the Swiss-type format, it is highly unlikely that a medical practitioner would make a patent claim for a 'pure' method. Rather, a surgeon who wishes to patent a new medical procedure involving therapeutic substances in Europe will almost certainly draft their claim in the Swiss-type format.

Swiss-type claiming is a creation of patent attorneys, accepted by courts as a means of providing an indirect way to secure patent protection for methods of therapeutic treatment. It means that an applicant can secure a claim to novelty through new therapeutic use, and can avoid the method of treatment exclusion by redrafting the claim to the manufacture of a medicament. It is a 'fiction' created by the courts to justify patent protection for a second or subsequent medical use directed to the medical treatment of humans and animals and has, as a result led to considerable debate both in the academic literature and in the courts.<sup>132</sup>

Although Swiss-type claiming is a solution to the problem of patentability of medical treatment, it suffers from lack of clarity as it is difficult, in practical terms, to define the validity and precise scope of a claim. This creates problems for potential infringers, since it is difficult to determine the nature of the act of infringement: is it the manufacture of the medicament, its use, or manufacture with a view to use?<sup>133</sup> Moreover, it leaves uncertainty for the public who need to know what they allowed to do with known compounds.<sup>134</sup>

In accepting Swiss-type claiming, the Courts and Patent Offices in Europe have clearly made a policy decision to allow indirect protection of certain methods of medical treatment, despite the express prohibition in European patent law. Looking back at Chapter 1, the main justification for the exclusion of methods of medical treatment in modern law would seem to be centered on ethical considerations. There is scope to consider such matters in European patent law in the form of the *ordre public* and morality exclusion. Indeed, when considering whether a claimed subject-matter should be given patent protection, examiners are obliged to consider whether the exploitation of the invention is against public interest or likely to seriously prejudice public security and/or cause serious damage to the environment. If so, the invention will be excluded from patenting for being contrary to Art 53(a). To date, this provision has not been considered by the Courts or the various EPO Boards with regard to methods of medical treatment. It will be proposed in Chapter 6 that provisions in Art 53(a) warrant further scrutiny with regard to inventions relating to methods of medical treatment. It will be proposed that this provision might provide a feasible alternative to the proviso of s 6 of the *Statute of Monopolies* located in s 18(1) of the *Patents Act 1990* (Cth), which treats the patent void if it is *contrary to the law, mischievous to the State, to the hurt of*

---

<sup>132</sup> See, eg, J Savina, 'The Patentability of the Second Therapeutic Application – Why must the Law by Changed?' (1995) 8 *Patent World* 32; *Bristol-Myers Squibb Co v Baker Norton Pharmaceuticals Inc* [1999] RPC 253.

<sup>133</sup> Savina, above n 118, 34.

<sup>134</sup> *Bristol-Myers Squibb Co v Baker Norton Pharmaceuticals Inc* [1999] RPC 253, 272.



*trade or generally inconvenient.* It will also be argued that a provision of this nature is more suitable than outright exclusion of methods of medical treatment. European experience shows that such outright exclusions can and will be worked around by skilled patent attorneys.

## CHAPTER 3: PATENTABILITY OF METHODS OF MEDICAL TREATMENT IN OTHER COUNTRIES OUTSIDE AUSTRALIA

### 3.1 INTRODUCTION

Chapters 1 and 2 revealed that in the UK there is long standing authority for the exclusion of methods of medical treatment, although the justification for such exclusion has changed over time. All European countries that are members of the European Patent Convention (*EPC*), including the UK, are required to have an express exclusion in their legislation. However, as Chapter 2 concludes, the value of the European exclusion is questionable because of the legal fiction created by Swiss-type claims. As a consequence, it will be argued that Australian legislators should be wary of introducing a provision of this nature into the *Patents Act 1990* (Cth).

Before discussing the patentability of methods of medical treatment in Australia, it is necessary to address the situation in other jurisdictions that have similar patenting system to Australia. This Chapter provides a review and comparative analysis of the common and statutory law of Canada, Israel, New Zealand and the US. Although the patent systems of these countries are no longer aligned the UK patent system, they are all derived from the same English patent legislation - the *Statute of Monopolies 1624*. It is intended that the analysis in this Chapter will assist in providing a backdrop against which the Australian position regarding patentability of methods of medical treatment is considered in Chapter 4. It will be suggested in later Chapters that the experiences of these countries, particularly Canada and the US, in the field of patenting of medical treatments might provide useful directions or alternatives in addressing issue of patentability of medical treatments in Australia.

This Chapter consists of six parts. In Parts 3.1 - 3.5 a brief review of the legislation, case law and patent office practice in each jurisdiction is provided. The key features of the law and practice regarding patenting of methods of medical treatments in the country under observation are summarised at the end of each part. A full account and comparative analysis of the reviewed laws and practice is made in the final Part 3.6. Hypothetical examples will be used in this part of the Chapter to illustrate how similar cases are treated differently in different jurisdictions.

## 3.2 CANADA

### 3.2.1 Relevant Statutory Provisions

In Canada the grant of patents is governed by the provisions of the *Patents Act*, R.S.C. 1985, P-4 (the **Canadian Act**). The Act provides for the patenting of inventions. An 'invention' is defined in s 2.as:

any new and useful art, process, machine, manufacture or composition of matter,  
or any new and useful improvement in any art, process, machine, manufacture or  
composition of matter.

Section 2 of the Canadian Act is a mirror provision of its predecessor, s 2 of the *Patent Act*, R.S.C. 1952. There is nothing in the Canadian Act that expressly excludes methods of medical treatment from patentability, and as a consequence the issue has been left to the courts to address. The position of the courts regarding this issue appears to be similar to the UK approach prior to the inclusion of an express exclusion in the *Patents Act* 1977 (UK) in compliance with the EPC. Accordingly, the Canadian courts have considering methods of medical treatment as inherently unpatentable, following the Supreme Court decision in *Tennessee Eastman Co v The Commissioner*.<sup>1</sup>

### 3.2.2 Case Law

#### 3.2.2.1 *Tennessee Eastman Co v The Commissioner*

In 1972 the Supreme Court of Canada had to decide whether a new surgical use for a known substance could be claimed as an invention under *Patent Act*, R.S.C. 1952, s 2(d). The inventor made an unexpected discovery that a previously known adhesive could be used in a new surgical method of joining or bonding the surfaces of incisions or wounds in living animal tissue by applying the compound in a liquid state, directly to at least one of the tissue surfaces to be bonded. Since the substance was already known, the claim was limited to the method.

The Examiner had refused a patent for the method on the basis that granting a monopoly on the use of the material would hamper the medical profession, and thus was not in the public interest.<sup>2</sup> This conclusion was upheld by the acting

---

<sup>1</sup> (1972) 33 DLR (3d) 459.

<sup>2</sup> Ibid, 460.

Commissioner in July 1968. Subsequently, the court of first instance affirmed the decision of the Commissioner, holding that the method under review did not lie in the field of manual or productive arts, nor, when applied to the human body, did it produce a result in relation to trade, commerce or industry or a result that was essentially economic.<sup>3</sup> Consequently, the court decided that the method was not an art or process or an improvement of an art or process within the meaning of the *Patent Act, R.S.C. 1952*, s 2(d).

On appeal, the Supreme Court's decision, delivered by Pigeon J, was not based on the reason that medical treatments could not satisfy the economic element, but on an interpretation of s 41(1) of the *Patent Act, R.S.C. 1952*. Section 41 restricted the granting of patents 'relating to substances prepared or produced by chemical processes and intended for food or medicine'. It might be supposed that this provision prohibited patenting of substances prepared by chemical processes and intended to be applied therapeutically but not their methods of preparation. However, the Supreme Court reasoned that if the medical substance was not patentable, neither was its use, and therefore, methods of medical treatment were excluded as well.<sup>4</sup>

In deciding this case, the court referred to UK,<sup>5</sup> New Zealand<sup>6</sup> and Australian<sup>7</sup> case law. However, due to substantial differences between the legislation in these countries and Canadian statutes, the court concluded that those authorities did not assist. Moreover, none of that case law related to a medical or surgical method as such. Pigeon J said that while those decisions could be of some interest in dealing with the patentability of inventions related to slaughtering or agricultural processes, they did not provide assistance in interpreting s 41(1) with respect to the exclusion of a surgical or medical method.

### 3.2.2.2 Decisions After the *Tennessee* Case

In 1985 s 41 of the *Patent Act, R.S.C. 1952* was repealed. Consequently new medical substances no longer needed to be limited to its use. Thus, it might be expected that the basis for the refusal to patent methods of medical treatment laid down by the court in the *Tennessee* case, would have disappeared. Yet, in reality it has not. In *ICI v The Commissioner*,<sup>8</sup> for example, the Federal Court of Appeal

---

<sup>3</sup> Ibid, 464 (Kerr J).

<sup>4</sup> Ibid.

<sup>5</sup> *Re Schering AG's Application* [1971] RPC 337; *Swift & Company's Application* [1962] RPC 37.

<sup>6</sup> *Swift & Co v Commissioner of Patents* [1960] NZLR 775.

<sup>7</sup> *National Research Development Corporation v Commissioner of Patents* (1959) 102 CLR 252.

<sup>8</sup> (1986) 9 CPR (3d) 289.

followed the *Tennessee* case, and held that a method of cleaning teeth involving the use of a known substance was a method of medical treatment. The court took this view because at least one of the leading functions or purposes of the cleaning of teeth was medical method, therefore unpatentable.

In 1996, the case of *Visx v Nidek*,<sup>9</sup> concerning a patent for a laser apparatus for performing ophthalmologic surgery, was decided by Rothstein J, of the Federal Court of Canada, Trial Division. The defendant argued that since the apparatus was designed to perform surgical procedures and since surgical procedures have been held to be inherently unpatentable in Canada, the patent claiming the apparatus must be invalid. However, Rothstein J, held that when the claim involves a medical *apparatus and its use* the claim did not constitute a method of medical treatment.<sup>10</sup> Consequently, the claim was upheld.

This decision raises a question as to whether a claim for an *apparatus and its use* is of the same nature as a claim for a method of medical or surgical treatment. The view taken by the Enlarged Board of Appeal of the European Patent Office,<sup>11</sup> the UK Patents Court<sup>12</sup> and, at that time, by the Patent Office of Canada,<sup>13</sup> was that a method of use of a medical apparatus or medical substance was considered to be a method of medical treatment. Rothstein J's judgment in *Visx v Nidek* would seem to be contrary to this line of authority. However, as was explained by one Canadian commentator, 'the use by Rothstein J of the words 'and its use' must be treated as inadvertent, and should not be considered as a change in the law.'<sup>14</sup> On this basis, it would seem that a claim to the apparatus itself would be patentable, but not a claim to the use of the apparatus in surgical procedures.

Notwithstanding Justice Rothstein's 'inadvertent' terminology in *Visx v Nidek*, since that case several rejections of applications for patents directed to inventions relating to the human body have been successfully appealed to the Patent Appeal Board of the Canadian Patent Office.<sup>15</sup> This suggests that the Board is willing to take a narrow view of the phrase 'medical treatment' in the strict sense, only disallowing patenting of pure surgical and therapeutic procedures, which require the use of professional knowledge.

<sup>9</sup> (1996) 66 CPR (3d) 178 (FCTD).

<sup>10</sup> *Visx v Nidek* 1996) 66 CPR (3d) 178 (Rothstein J).

<sup>11</sup> See *Eisai/Second Medical Indication* (1985) OJ EPO 60.

<sup>12</sup> *John Wyeth & Brother Ltd's Application and Schering A.G's Application* [1985] RPC 545.

<sup>13</sup> B Garland, 'Methods of Medical Treatment Revised' (1997) 8 *Patent World* 1, 8; Canadian Patent Office, *Manual of Patent Office Practice* (1998), Government of Canada, Ottawa, see <http://patents1.ic.gc.ca/> (date accessed: 15 September 2007).

<sup>14</sup> Garland, above n 16, 8.

<sup>15</sup> See *Re Application* No. 016, 962; *Re Application* No. 880, 719; *Re Application* No. 372,233.

### 3.2.3 'Use Of Claims

Though pure methods of medical treatment are not directly patentable in Canada, it has been suggested by Canadian Patent and Trademark Agents<sup>16</sup> that such methods can be patented indirectly. Making general patent claims for the *use of* a drug or device and omitting the step of performing a medical procedure or administering a drug can still protect this type of invention. This type of claim would not purport to incorporate the professional skill needed to constitute a method of medical treatment. Like the Swiss-type claims in Europe, these *use of* claims has become very popular in Canada.

The Trial Division of the Federal Court of Canada in *Merck & Co v Apotex*<sup>17</sup> made it clear that claims to pharmaceutical compounds and compositions are not equivalent to claims for methods of medical treatment. The situation, however, is not clear in respect of second medical use. As noted in *Apotex v Wellcome*<sup>18</sup> such patents might be seen to lie in between methods of medical treatment and compounds used in methods of medical treatment. Since in second medical use claims, the compound is not new, the only scope for the patent claim remains in the *new use* of that compound in a course of treatment. According to *Apotex v Wellcome*<sup>19</sup> it was at least arguable that a claim for a *new medical use of a known substance* was, in effect, a method of medical treatment and could be potentially denied patent protection.

### 3.2.4 Summary of Canadian Position

This brief review of the Canadian legislation and case law indicates that methods of *surgical* and *prophylactic* treatments are not patentable in Canada.<sup>20</sup> This approach results in a similar outcome to the express exclusion of surgical and therapeutic methods adopted in Europe under Art 52(4) EPC, first sentence. However, as a claim to the apparatus itself would be patentable, it follows that, unlike Europe, *diagnostic* methods may be patentable in Canada.<sup>21</sup>

---

<sup>16</sup> See <http://patents1.ic.gc.ca/> (date accessed: 5 October 2007); Deeth Williams Wall LLP - Patent and Trade Mark agents: [www.dww.com](http://www.dww.com) (date accessed: 25 August 2007).

<sup>17</sup> (1995) 59 CPR (3d) 133.

<sup>18</sup> (1996) 68 CPR (3d) 23.

<sup>19</sup> Ibid.

<sup>20</sup> *Re Application of Ackerman* (1977) 105 CPR 14-xviii.

<sup>21</sup> *Visx v Nidek* 1996) 66 CPR (3d) 178; *Re Application for patent of Goldenberg* (1988) 22 CPR 159.

Furthermore, while a pharmaceutical substance that would be used in preventing or treating a medical condition of a patient could be patented in Canada, the treatment itself would be unpatentable. This distinction is questionable as the patentable compound usually consists of the drug itself and its use of treatment. The rationale behind the distinction is based on the view that the treatment consists of the judgment applied by the physician on a case-by-case basis as to the dose and duration of therapy that is required to treat the particular patient, and the drug compound is merely a substance used in this treatment.<sup>22</sup> Accordingly, while the compound for a particular use or uses is patentable, the treatment consisting of the application of the patentable compound is not.

It could be argued, therefore that in Canada, since a method of medical treatment is distinguished from the *use of* a compound in that treatment, there remains a fair amount of latitude for patenting the compounds and devices used in medical treatments.

### 3.3 ISRAEL

#### 3.3.1 Relevant Statutory Provisions

In Israel the relevant patent legislation is the *Patents Act 1967* (the ***Israeli Act***). Section 3 defines patentable subject matter and includes inventions that are susceptible to industrial or agricultural application. Industrial applicability has been broadly interpreted and practically all commercially important inventions are considered today as being 'industrially applicable'.<sup>23</sup>

Section 7 of the Israeli Act lists several express exclusions from patentability, including methods of therapeutic treatment of the human body, new varieties of plants and animals and microbiological organisms derived from nature. It states, in part: 'Notwithstanding the provision of Section 2, no patent shall be granted for - (1) a methods of therapeutic treatment of the human body'.

It must be noted that the previous law, the *Mandatory Patents and Designs Ordinance 1924* (the ***Israeli Ordinance***), contained no express prohibition on patenting of methods of medical treatment, and in the absence of any statutory directives, the issue was considered by the courts. In the administration of the

---

<sup>22</sup> *Merck & Co v Apotex* (1995) 59 CPR (3d) 133.

<sup>23</sup> See general reports of the International Association for the Protection of Intellectual Property <http://www.aippi.org> (date accessed: 20 September 2007).

Ordinance the Israeli courts were guided by the relevant English legislation at the time, the *Patents and Designs Act 1949* (UK), which also did not explicitly exclude medical method patents.

### 3.3.2 Case Law

The issue of patentability of methods of medical treatment of humans was raised before the Supreme Court of Israel in 1973 in *Wellcome Foundation Ltd v Plantex Ltd*<sup>24</sup> (***Wellcome Foundation***). The case involved an action for infringement of a patent relating to the use of a known chemical substance, allopurinol, in the treatment of gout. The defendants, Plantex, challenged the validity of the patent on a number of grounds, particularly upon the allegation that the invention was excluded from patentability in that it concerned a method of medical treatment of humans. Plantex also argued that the antimetabolic activity of allopurinol was known and that no new properties were disclosed or claimed by the patent.

Since the patent had been granted before the Israeli Act came into force, the issue about patentability of medical treatment and the validity of patent was decided under the previous law, the Ordinance. It was agreed by the defendants that in the general administration of the Ordinance, the Israeli Courts should be guided by UK law. Although UK courts had accepted that there was a treatment exception in that jurisdiction, the court of first instance in *Wellcome Foundation* held that the UK exception derived from UK Patent Office practice, not law. On this basis, the court found in favour of the plaintiff, Wellcome Foundation, holding that the patent was valid and infringed.

The defendant unsuccessfully appealed to the Israeli Supreme Court. The judges of the Supreme Court agreed that although Israel should generally be guided by English law, the practice of the UK Patent Office was not binding on the Israeli courts in the interpretation of the Ordinance. Thus, the court was free to consider this question on its merits.<sup>25</sup>

Witkon J delivered the leading judgment. The first inquiry His Honour dealt with was whether there was patentable subject matter in the discovery of novel properties in a known substance, which discovery enabled the application of the substance for new and useful purposes. His Honour had no doubt that the reply to this inquiry should be in the affirmative. In support of his view, Witkon J referred to the Australian landmark judgment in the matter of *National Research Development*

---

<sup>24</sup> [1974] RPC 514, published in Hebrew in PDI (Supreme Court Judgments), vol. 27, 29.

<sup>25</sup> *Wellcome Foundation Ltd v Plantex Ltd* [1974] RPC 514, 533.



*Corporation v Commissioner of Patents*<sup>26</sup> (*NRDC*), from which it followed that although in the past there had been opinions against the grant of a patent for such an invention, the patentability of such an invention could no longer be challenged.<sup>27</sup>

Witkon J then turned to the question of whether it was possible to obtain a patent on a method of medical treatment of humans. Even though it was found in the affirmative that there was an invention, the appellant argued that the invention merely consisted of finding a new use for an old substance, allopurinol. The appellant further argued that since the inventive step resided in the new use, the patent was directed to the method of medical treatment itself, and was therefore not patentable. Here Witkon J was again guided by *NRDC*. Although that case focused on patenting of agricultural process, it assisted Witkon J for what it said about English Patent Office practice regarding interpretation of the word 'invention'.<sup>28</sup> In *NRDC* the Australian High Court disagreed with such practice and did not follow its decisions. On this basis, Witkon J did not hesitate to disregard the practice of exclusion of medical treatment patents. After reviewing the case law on this matter, he concluded that the rule by which no patent is granted for methods of medical treatment of humans is not desirable, since 'there is nowadays a tendency in favour of inventors in order to foster and support science and to ensure a proper reward to the investigator and investor'.<sup>29</sup> Witkon J continued:

There is no logic in such an exclusion as long as it is lawful to obtain a patent on a pharmaceutical product, since in both cases there is an equal need for patent protection. ... There is thus no ground, either in law or in logic, for holding that a methods of therapeutic treatment is unpatentable and any consideration that at one time might possibly have justified such a holding, is nowadays devoid of any substance. It may certainly not be said that such an invention is not within the realm of economic endeavour in accordance with the test laid down in *NRDC* [1961] RPC 134, or that it is within the realm of 'fine art' as distinct from 'useful art'.<sup>30</sup>

Both Kahn and Kister JJ agreed with Witkon J on the point that the Israeli courts were not bound by the English Patent Office practice because of the different statutory provisions in the two countries. However, both expressed reservations

---

<sup>26</sup> (1959) 102 CLR 252.

<sup>27</sup> *Wellcome Foundation Ltd v Plantex Ltd* [1974] RPC 514, 519.

<sup>28</sup> See *National Research Development Corporation v Commissioner of Patents* (1959) 102 CLR 252, 270-272, 277. See also the discussion of *NRDC* in Chapter 4, Parts 4.4.2 and 4.5.1.2.

<sup>29</sup> *Ibid*, 536.

<sup>30</sup> *Ibid*.

about the creation of a monopoly by a patent in respect of areas concerned with saving human life or alleviation of human suffering.

Since this case was heard after the new *Patents Act* 1967 came into force, which explicitly prohibited patents for methods of medical treatment of humans, Witkon J's judgment was the last contribution to the debate about granting patent protection to methods of medical treatment in Israel. It is perhaps unfortunate that the case was decided after the new legislation was debated and enacted by the Israeli Parliament. Otherwise, the case might have influenced legislators in making their decisions as to whether or not to accept the inclusion of the method of medical treatment exclusion in the new legislation.

### 3.3.3 'Use Of Claims

Similarly to the position in Europe, the ban on the patentability of methods of medical treatment in Israel has caused problems where a known substance already used to treat a particular medical condition is found to be useful in treating some other medical condition. In Europe, where methods of medical treatment are also unpatentable, the Swiss-type claim was devised to enable second medical uses to obtain some patent protection.

In Israel, according to the Practice Directives of the Registrar made in 1993 and still in force at the present time,<sup>31</sup> a claim in the form 'Use of X in the manufacture/preparation of Y' is considered to be a process claim and as such complies with s 3 of the Israeli Act.<sup>32</sup> For a first medical use, the claim in the form 'Use of X in the manufacture/preparation of a medicament substantially as described in the specification' would be *prima-facie* acceptable. In addition, the claim 'Compound X for use as a medicament' would also be considered to comply with the provisions of the Israeli Act.<sup>33</sup>

For a second medical use to be allowable it is necessary to specify such new use embodying the inventive step, for example: 'Use of X in the manufacture/preparation of a medicament having anti-inflammatory activity substantially as described in the specification'.<sup>34</sup> The following forms would be also allowable: 'Compound X for use as anti-inflammatory agent', or 'Compound X for use in the treatment of Aids'.

<sup>31</sup> See Israel Patent Office Claims Practice in Materials, Chemical and Pharmaceutical Cases- Part II (Claims Practice).

<sup>32</sup> Claims Practice, Directive No.38.

<sup>33</sup> Claims Practice, Directive No.40.

<sup>34</sup> *Ibid.*

### 3.3.4 Summary of Israeli Position

The Israeli position is different from that of the Canadian as the Israeli Act expressly prohibits patenting of methods of medical treatment by virtue of s 7. This approach is similar to that of the UK and Europe. Furthermore, the approach taken with regards to the first and second medical use is similar to the UK and European approach – a pharmaceutical substance, whether itself, or in respect of second medical use will be patentable.

## 3.4 NEW ZEALAND

### 3.4.1 Relevant Statutory Provisions

In New Zealand, the grant of patents is governed by the provisions of the *Patents Act 1953* (the **NZ Act**). The Act contains no express prohibition for methods of medical treatment. The question of patenting of such methods has been reserved for the courts to decide. The courts, therefore, have to determine whether methods of medical treatment fall within the meaning of 'invention' under s 2 (1) of the NZ Act, which provides:

'Invention' means any manner of new manufacture the subject of letters patent and grant of privilege within s six of the Statute of Monopolies and any new method or process of testing applicable to the improvement or control of manufacture; and includes an alleged invention.

'The Statute of Monopolies' means the Act of the twenty-first year of the reign of King James the First, chapter three, entitled 'An Act concerning monopolies and dispensations with penal laws and the forfeiture thereof'.

The New Zealand legislation has been under review for possible reform since 1990.<sup>35</sup> In 1992 and in 1994, after considering the reform process the Ministry of Commerce recommended that the current definition of 'invention' be repealed.<sup>36</sup> The Ministry proposed that the three criteria - newness, inventive step and industrial applicability - should determine a patentable invention. This approach

---

<sup>35</sup> Philip Culbert, 'Patent Law Reform in New Zealand: Should Methods of Medical Treatment be Patentable?' (1997) *Patent World* 32; Todd Martin, 'Patentability of Methods of Medical Treatment: A Comparative Study' (2000) 82 *Journal of the Patent & Trademark Office* 381.

<sup>36</sup> *Reform of the Patents Act 1953 Proposed Recommendations* (Ministry of Commerce, Wellington, 1992).

would have brought New Zealand standards of patentability into line with those in the EPC. However, the Ministry also recommended that there should be no exclusions from patentability, a view significantly different from that adopted by the EPC. It also proposed an Intellectual Property Law Reform Bill to implement the above recommendations.<sup>37</sup>

It has been argued that the effect of these changes would have been to allow patents for methods of medical treatment.<sup>38</sup> However, due to internal government changes and other delays, the proposals have never been implemented. Policy approval was given in August 2000 for a new three-stage review of the Act by the Ministry of Economic Development. The reason for three stages was to break such a major reform project into more manageable pieces. To date, the review of patent legislation continues with the release of the draft Patents Bill in December 2004. The Bill is yet to be passed in Parliament. The new legislation is not expected to come into force until 2008.

The most significant changes relate to the requirements for patentability. Under the Bill an invention must be novel, inventive (ie, non-obvious) and useful in order to receive patent protection. These amendments bring the New Zealand patent examination criteria into accordance with international patent examination requirements. The Bill will also introduce exclusions from patentability for 'human beings and biological processes for their generation' and 'diagnostic, therapeutic or surgical methods for the treatment of human beings', as well as plant varieties.<sup>39</sup> For the present, however, the NZ Act remains in force and given that it is silent on the patentability of methods of medical treatment it is necessary to review the case law.

### 3.4.2 Development of New Zealand Case Law

Since under New Zealand patent law an alleged patent must fall within the meaning of 'invention', the courts must first decide whether it is a 'manner of new manufacture' within s 6 of the *Statute of Monopolies*. This approach is identical to the one used by the English courts under the *Patents and Designs Act 1949* (UK), and, as we will see in Chapter 4, by the Australian courts under current Australian patent law.

---

<sup>37</sup> Tom Sydall, 'Method of Treatment Claims and Patent Law Reform in New Zealand' (1996) *The Chartered Institute of Patent Attorneys Journal* 423.

<sup>38</sup> Sydall, above n 36.

<sup>39</sup> New Zealand Ministry of Economic Development, *A Review of the Patents Act 1953: Boundaries to Patentability: A Discussion Paper* (2002), New Zealand, see [www.med.govt.nz/buslt/int\\_prop/patentsreview/index.html](http://www.med.govt.nz/buslt/int_prop/patentsreview/index.html) (date accessed: 15 October 2007).

New Zealand case law reveals the same progressive approach to the manner of manufacture concept as adopted in the UK. The early cases dealing with medical inventions patents and the phrase 'manner of new manufacture' adopted the same interpretation of the concept as English courts after the decision *In the Matter of C & W's Application for a Patent*<sup>40</sup> (***C & W's Application***), where the court refused the application for method of medical treatment since it did not employ any form of manufacture or of trade, and thus lacked commercial value.<sup>41</sup>

#### 3.4.2.1 ***Maeder v 'Ronda' Ladies' Hairdressing Salon***<sup>42</sup> (***Maeder***)

This case involved an action for infringement of a patent granted in respect of an improved process of, and means for, producing permanent waves on hair growing on the human head. In the lower court, giving judgment for the defendants on the ground that the patent was invalid for technical reasons, Smith J nevertheless was of the opinion that a process for the permanent waving of the human hair on the scalp may be 'a manner of new manufacture'.

On appeal in the Court of Appeal, Myers CJ and Johnston J held that for a process to be patentable, if it did not produce a vendible art, it must at least have relation in some way, directly or indirectly, to the production of a vendible art, an art of commerce. Thus, a process for 'permanent waving' of hair growing on the human head was not patentable, as it did not result in the production of a vendible art, an art of commerce. In so ruling the court followed the principles set out in *C & W's Application* (1914) 31 RPC 235.<sup>43</sup>

#### 3.4.2.2 ***Swift & Co v Commissioner of Patents***<sup>44</sup>

In this case the court considered whether a new method of 'tenderizing' meat through enzymatic action was 'a manner of manufacture' within the meaning of s 6 of the *Statute of Monopolies*. This case was decided after the Australian High Court decision in *NRDC*, and clearly followed the reasoning of the court in that case.<sup>45</sup> In delivering his judgment, Barrowclough CJ referred with approval to the following observation of the Australian High Court:

---

<sup>40</sup> (1914) 31 RPC 235.

<sup>41</sup> *Ibid.*, 236.

<sup>42</sup> [1943] NZLR 122.

<sup>43</sup> *Maeder v 'Ronda' Ladies' Hairdressing Salon* [1943] NZLR 122, 123.

<sup>44</sup> [1960] NZLR 775.

<sup>45</sup> It must also be pointed out that a few months later, a similar patent application was decided before the Patent Appeal tribunal in UK, *Swift's & Co's Application* [1961] RPC 129 discussed in Chapter 1 Part 1.3.3.

It is, we think, only by understanding the word 'product' as covering every end product produced, and treating the word 'vendible' as pointing only to the requirement of utility in practical affairs that the language of Morton J's 'rule' [in the *GEC* case (1942) 60 RPC 1] may be accepted as wide enough to convey the broad idea which the long line of decisions on the subject has shown to be comprehended by the Statute.<sup>46</sup>

Even though the process of 'tenderizing' meat was not related to an agricultural or horticultural enterprise, and was a biological invention, the Chief Justice pointed out that the conclusion reached in *NRDC* was as applicable to biological inventions as it was to horticultural and agricultural enterprises. He stated that if the alleged invention fell with a specific category, one could not negate patentability of that invention solely on the ground that the process is within that category.<sup>47</sup> Barrowclough CJ concluded that though the process at issue was not within the ordinary everyday concept of 'manufacture', it was clearly a 'manner of manufacture' because the phrase 'must be interpreted in relation to a modern word's ever expanding knowledge of science and technology.'<sup>48</sup>

In reaching his decision, Barrowclough CJ did not refer to the earlier case of *Maeder*. For this reason, in a later decision of the Patent Office<sup>49</sup> the Assistant Commissioner expressed some doubt as to whether Barrowclough CJ was correct in law in coming to the decision that he did. It is also noteworthy that the decision of Barrowclough CJ was not followed in the following year in the UK by Lloyd-Jacob J, when he refused a patent for a similar process of 'tenderizing' meat in the UK *Swift* case.<sup>50</sup>

### 3.4.2.3 *Wellcome Foundation Ltd v Commissioner of Patents*<sup>51</sup> (*Wellcome*)

Wellcome Foundation Ltd made an unexpected discovery that a previously known compound (which was not patentable per se) was considerably effective in the treatment of meningeal leukemia or neoplasms in the brain of humans and other mammals. Previously known drugs used in contemporary antileukemic therapy did not pass the blood-brain barrier with the result that the central nervous system

---

The facts of the case were identical to the UK *Swift* case. However, unlike the decision in the NZ *Swift*, Lloyd-Jacob J in the UK *Swift* case refused a patent for a similar process.

<sup>46</sup> *National Research Development Corporation v Commissioner of Patents* (1959) 102 CLR 252, 276.

<sup>47</sup> *Swift & Co v Commissioner of Patents* [1960] NZLR 775, 779.

<sup>48</sup> *Ibid*, 781.

<sup>49</sup> *Wellcome Foundation Ltd v Commissioner of Patents* [1979] 2 NZLR 591.

<sup>50</sup> See discussion of the UK *Swift* case in Chapter 1, Part 1.3.3.

<sup>51</sup> [1979] 2 NZLR 591.

could serve as a sanctuary for leukemic cells, resulting in the probability that the patient would develop meningeal leukemia. The new discovery could overcome this problem, because the compounds were capable of crossing the blood-brain barrier and concentrating within the brain. However, since the product itself was already known and not patentable, the subject matter of the alleged invention had to be restricted to a method of treating meningeal leukemia or neoplasms in the brain such as lymphoma of the central nervous system, and the preparations used for such treatment. The examiner rejected the application, following the decision in *Maeder*. He concluded that the method claimed did not relate to an invention within the meaning of the NZ Act, s 2, as they related to a method of treatment of man and thus did not result in a vendible product.<sup>52</sup>

The Chief Justice, Sir Ronald Davison, handed down the judgment of the Supreme Court in 1979. Davison CJ examined relevant authorities from New Zealand, the UK, Australia and Israel. From this examination he concluded that there was neither statutory provision nor court decision prohibiting the grant of a patent protection for methods of medical treatment in New Zealand.<sup>53</sup>

The Chief Justice pointed out that there was no case in the Australian jurisdiction where a matter concerning patenting of such methods has arisen for consideration. Though in the *NRDC* and *Joos v Commissioner of Patents*<sup>54</sup> (*Joos*) Australian High Court judges have referred to such methods, they expressed doubts about their patentability. For example, in *NRDC* a small remark was made about methods of medical treatment: 'even if only in order to put aside, as they apparently must be put aside'.<sup>55</sup> In *Joos* Barwick CJ allowed methods of medical treatment of a cosmetic nature but expressed no clear view as to whether methods of medical treatment were excluded. The Chief Justice discussed the exclusion in carefully worded phrases such as '[f]or the purpose of deciding this question it may be granted',<sup>56</sup> 'if it to be accepted',<sup>57</sup> and 'if it is to be maintained'.<sup>58</sup>

The review of English case law led Davison CJ to conclude that *Schering*,<sup>59</sup> *Eli Lilly*<sup>60</sup> and *Upjohn*<sup>61</sup> did not provide a satisfactory basis on which to prevent the

---

<sup>52</sup> *Wellcome Foundation Ltd v Commissioner of Patents* [1979] 2 NZLR 592.

<sup>53</sup> *Ibid*, 620.

<sup>54</sup> (1972) 126 CLR 611.

<sup>55</sup> *National Research Development Corporation v Commissioner of Patents* (1959) 102 CLR 252, 270.

<sup>56</sup> *Joos v Commissioner of Patents* (1972) 126 CLR 611, 619.

<sup>57</sup> *Ibid*, 622.

<sup>58</sup> *Ibid*, 623.

<sup>59</sup> *Schering AG's Application* [1971] RPC 337.

<sup>60</sup> *Eli Lilly & Company's Application* [1975] RPC 438.

<sup>61</sup> *Upjohn Company (Robert's) Application* [1977] RPC 94.

development of the law relating to patentability of methods of medical treatment in New Zealand. In commenting those decisions, he said:

The considerations which persuade me that there is no impediment in law to grant of a patent for a process for the medical treatment ... appear not to have been argued fully before the Courts in these cases.<sup>62</sup>

The Chief Justice continued that in *Schering* and *Joos* 'the Courts established distinctions without a difference'.<sup>63</sup> His Honour put the matter in this way:

Is there any justification in law or in logic to say that simply because, on the one hand, substances produce a cosmetic result or a functional result as opposed to a curative result, the one is patentable and the other is not? I think not. The Court must now take a realistic view of this matter in the light of current scientific developments and legal progress. The law must meet the needs of the age.<sup>64</sup>

Following on from this analysis, Davison CJ felt no hesitation in passing over the barrier of so called 'non-patentability' and holding that a method of medical treatment may be the subject of a patent under the New Zealand *Patents Act 1953*.

In his consideration of the proviso of s 6 of the *Statute of Monopolies* - that requires the method concerned not to be contrary to the law, or mischievous to the State, by raising prices of commodities at home or hurt of trade, or generally inconvenient - Davison CJ noted that the method in the issue was not contrary to the law. He added that in *Eli Lilly* the basis on which a method of medical treatment has been denied patent protection for many years was because such a grant might be 'mischievous to the State or generally inconvenient', and the denial was based on 'ethics rather than logic'.<sup>65</sup>

Davison CJ strongly disagreed with this view and stated that an examination of the development of the law on this topic indicated that the exclusion was based solely on the Patent Office practice, which existed prior to the *C & W's Application* in 1914 and that Lord Buckmaster's decision in *C & W's Application* simply reaffirmed the practice. Ethical considerations did not apply.<sup>66</sup> The Chief Justice continued:

---

<sup>62</sup> *Wellcome Foundation Ltd v Commissioner of Patents* [1979] 2 NZLR 591, 621.

<sup>63</sup> *Ibid*, 621.

<sup>64</sup> *Ibid*.

<sup>65</sup> *Eli Lilly & Company's Application* [1975] RPC 438, 445.

<sup>66</sup> *Wellcome Foundation Ltd v Commissioner of Patents* [1979] 2 NZLR 591, 619-620.



Now the foundation for the decision in the *C & W* case has been removed by subsequent decisions, the Courts have been grasping for some other ground on which to base a refusal to exclude process for medical treatment from patent protection. I find no warrant in law for grounding such refusal on ethical considerations.<sup>67</sup>

In support of this conclusion, the Chief Justice said that since the researchers who discovered that new properties and new uses exist for known chemicals cannot obtain any patent protection for the chemicals themselves, they must be provided with other incentives for expending the time, effort and money to make such discoveries. Those incentives can only be created if a patent protection is available for new methods of medical treatment.<sup>68</sup>

The Commissioner of Patents appealed the decision of Davison CJ to the Court of Appeal.<sup>69</sup> Somers J, after reviewing English case law, the law of the EPC and the New Zealand case law on this matter, concluded that logic is not always a safe guide to the law, especially in the case of methods of medical treatment. This is because the treatment of human beings is of a special character, and it might be 'generally inconvenient' to grant a patent protection for methods of such treatment.<sup>70</sup>

McMullin J admitted that patent protection might encourage research for new methods of medical treatment. Therefore, human suffering may be alleviated to the greater good of mankind. However, his Honour also pointed out that, on the other hand, the grant of a patent is the grant of a monopoly and may lead to abuse. Therefore, a shift in emphasis that favours one interest might be achieved only at the expense of the other. For these reasons, his Honour concluded that it was not for the court, but for the Parliament, to decide whether, and to what extent, any significant innovative movement was justifiable.<sup>71</sup>

The third member of the Court of Appeal, Cooke J (as he then was) reached a similar conclusion. He said that while there have been developments in the law concerning this matter, they have not been acted upon, except in the judgment of Davison CJ. His Honour added that logically, no doubt, this approach could go so far, but the field of medical or surgical treatment and drugs is one in which special

---

<sup>67</sup>Ibid, 620.

<sup>68</sup> Ibid.

<sup>69</sup> *Commissioner of Patents v Wellcome Foundation Ltd* (1983) 1 IPR 156.

<sup>70</sup> Ibid, 164.

<sup>71</sup> Ibid, 172.

considerations have to be born in mind.<sup>72</sup> He concluded that the art of the physician or the surgeon in alleviating human suffering does not belong to the area of economic endeavour or trade and commerce.

The decision of the New Zealand Commissioner of Patents to appeal from Davison CJ's decision warrants some further consideration. Since the function of the Patent Office is to administer the patent law as it is, and not to seek to influence it, it has been argued that the case should have been decided on its facts.<sup>73</sup> That is, once the court had decided that the invention satisfied all the requirements of the New Zealand legislation, as Davison CJ concluded it did, the Commissioner should have simply accepted this decision and granted the patent.

#### 3.4.2.4 The Practice of the New Zealand Patent Office<sup>74</sup>

Following the *Wellcome* case, the New Zealand Patent Office continued to refuse patent applications for methods of medical treatment of the human body. However, claims for methods of cosmetic treatment have since been allowed.<sup>75</sup> Moreover, developments in patent law around the world were reflected in a Commissioner's Practice Note issued in October 1998<sup>76</sup> (*Practice Note*) where it was stated that claims for methods for treatment of humans would be allowed except where the identified treatment related to the treatment of illness or disease.

This practice, which must be read in conjunction with the appeal decision in the *Wellcome* case, allows patenting of some treatment of humans, which appears to include claims to the treatment of conditions that do not cause suffering or that might be matters of choice.

---

<sup>72</sup> Ibid, 175.

<sup>73</sup> See, eg, A. White, 'Patentability of Medical Treatment Wellcome Foundation's (Hitching's) Application' (1980) 11 *European Intellectual Property Review*, 364, 366.

<sup>74</sup> Since 1 August 1997, the New Zealand Patent Office was renamed as the Intellectual Property Office of New Zealand (IPONZ).

<sup>75</sup> Martin, above n 34, 394; *Joseph Handelman's Application*, NZPOJ No. 1367, Vol.82, issue No.3 (23 April 1993).

<sup>76</sup> IPONZ Practice Note, October 1998. See: <http://www.iponz.govt.nz/pls/web/dbssiten.main>, (date accessed: 15 October 2007).

### 3.4.3 'Use Of' Claims

#### 3.4.3.1 *Pharmaceutical Management Agency Ltd v Commissioner of Patents*<sup>77</sup>

This broad approach of the New Zealand Patent Office was confirmed by the recent judgment in *Pharmaceutical Management Agency Limited v Commissioner of Patents*<sup>78</sup> (*Pharmaceutical Management Agency*), where the Court of Appeal stated that methods of medical treatment are now considered to be 'inventions' in New Zealand, and their exclusion is only based on public policy grounds.<sup>79</sup> This case also upheld the validity of Swiss-type claims for new uses of known substances.

This case arose as a result of a Practice Note issued by the Commissioner on 7 July 1997 which reviewed Patent Office practice, in the light of the continuing international trends to liberalise the definition of 'invention'. The Commissioner came to the conclusion that it was appropriate that the Swiss-type claims should be allowed. The Practice Note also stated that claims to therapeutic treatment of human would continue to be disallowed. At around the same time, the Patent Office began accepting Swiss-type claims directed to the 'use of a known compound X in the manufacture of a medicament for a new therapeutic use'. However, shortly after the Practice Note was released, Pharmaceutical Management Agency Ltd (*Pharmac*) filed an application for judicial review in the High Court, seeking an order setting aside the practice decision, any accepted patent applications which had not yet progressed to the granting of a patent and any patents which, by the time the proceeding was heard, may have been granted as a result of the practice decision.<sup>80</sup>

Pharmac is the body responsible for managing the public funding and subsidization of medicines in New Zealand. It strongly advocated the view that grants of patents for inventions in respect of second or subsequent uses of pharmaceutical compounds could prevent competition among pharmaceutical suppliers, with adverse effects on the pricing of pharmaceuticals.<sup>81</sup> It challenged the right of the Commissioner of Patents to accept patents drafted in the Swiss-type form. If successful, the orders sought by Pharmac would have resulted in granted patents

---

<sup>77</sup> [1999] NZCA 332.

<sup>78</sup> Ibid.

<sup>79</sup> Ibid, 333. See further discussion regarding this point.

<sup>80</sup> Ibid, 333.

<sup>81</sup> Ibid, 334-5.

being revoked for some 24 international pharmaceutical companies and the Researched Medicines Industry Association of New Zealand (*RMI*). Although the New Zealand Commissioner of Patents was named by Pharmac as the defendant, the affected pharmaceutical companies and RMI reached an agreement that they would also join as defendants.

#### **(a) The Judgment of Gallen J in the High Court**

In the High Court Pharmac argued that a Swiss-type claim is simply a way around methods of medical treatment exception. Pharmac also relied on some obiter observations of the Court of Appeal in the *Wellcome* case. Gallen J rejected Pharmac's submission that since the Court in the *Wellcome* case held that no method of use in medical treatment could be patented, it was obvious that a medicament could not be patented for a second use.

Gallen J accepted that all three judges in *Wellcome* had expressed the view that although it was accepted that a substance intended for use in treatment was entitled to a protection for a first use, it was not so entitled for a second or subsequent use. However, he distinguished *Wellcome* by noting that the question before the court in *Wellcome* was whether or not *methods* of treatment, where a first therapeutic use of a known substance was used, were in fact, patentable. The distinction between *methods* of treatment and *substances* intended to be used for such treatment was never analysed.

Since the court in *Wellcome* did not finally determine the question in issue, Gallen J stated that the conclusion in that case was not necessarily helpful for the determination of the case before him.<sup>82</sup> Thus, it was appropriate to look at subsequent developments in the international patent law. In doing so, Gallen J found the EPO decision in *Re Eisai* (Decision Gr 05/83)<sup>83</sup> (*Eisai*) of particular interest, though admitting that the case was not decisive of a matter arising in New Zealand because the practice of the EPC differed from the practice in New Zealand. Nevertheless, Gallen J stated that in so far as it involved a logical analysis, it had significance and supported the position for the defendants.<sup>84</sup> Looking at the rationale for Swiss-type claims, Gallen J noted that the decision in *Re Eisai* did not run contrary to the conclusions in the *Wellcome* case.

---

<sup>82</sup> *Pharmaceutical Management Agency Ltd v Commissioner of Patents*, CP. 141/98, 17 December 1998 (NZHC), 15.

<sup>83</sup> *Eisai/Second Medical Indication* (1985) OJ EPO 60.

<sup>84</sup> *Pharmaceutical Management Agency Ltd v Commissioner of Patents*, CP. 141/98, 17 December 1998 (NZHC), 28.

After referral to the evidence and the competing claims for public interest Gallen J concluded that the positions of the plaintiffs and the defendants in this regard might be said to be equally supportable. Ultimately, His Honour held in favour of patentability of Swiss-type claims.<sup>85</sup>

#### **(b) The Court of Appeal<sup>86</sup>**

In the Court of Appeal, Pharmac submitted a different argument. It accepted that a Swiss-type claim was not a method of medical treatment claim. The new argument presented by Pharmac was that the European basis for finding *novelty* in a Swiss-type claim rested in Arts 52(4) and 54(5), provisions which were not part of, or analogous to, New Zealand legislation. Moreover, it was noted that *Eisai* had been the subject of growing criticism amongst patent lawyers.

Pharmac placed considerable reliance on the obiter observations made by the court in the UK in *Wyeth* and *Schering*<sup>87</sup>, which stated that the lack of novelty provided real difficulty to accepting the Swiss-type claim. The UK Court in *Wyeth* and *Schering* pointed out that the device of putting a claim into Swiss-type was not sufficient to confer novelty.<sup>88</sup> Although the UK Court ultimately followed *Eisai*, Pharmac pointed out that the reason for this was the desirability of achieving conformity in the EPC, and in fact the UK Court preferred the other view. The concern expressed by Jacob J in *Bristol-Myers Squibb Co v Baker Norton Pharmaceuticals Inc*<sup>89</sup> about the problems created by Swiss-type claims was also drawn to the Court's attention. In *Bristol Myers*, Jacob J had to consider the validity of a Swiss-type claim and expressed great reluctance in following the *Eisai* decision. His Honour found the patent invalid for want of novelty and obviousness.

Pharmac also argued that the grant of Swiss-type claims would be 'generally inconvenient' within the meaning of s 6 of the Statute of Monopolies, and that the issue of extension of patent protection to this type of claim was better left for Parliament.<sup>90</sup>

The pharmaceutical companies, on the other hand, argued that if the comments made in the *Wellcome* case led the Court to conclude that Swiss-type claims were

---

<sup>85</sup> *Pharmaceutical Management Agency Ltd v Commissioner of Patents*, CP. 141/98, 17 December 1998 (NZHC), 35.

<sup>86</sup> *Pharmaceutical Management Agency Ltd v Commissioner of Patents* [1999] NZCA 330.

<sup>87</sup> *John Wyeth & Brother Ltd's Application* and *Schering A.G's Application* [1985] RPC 545.

<sup>88</sup> *Ibid*, 565.

<sup>89</sup> [1999] RPC 253.

<sup>90</sup> *Pharmaceutical Management Agency Ltd v Commissioner of Patents* [1999] NZCA 330, [32].

not valid, then the whole reasoning of *Wellcome* should be reviewed.<sup>91</sup> However, it was also submitted that it would not be necessary to go that far since Swiss-type claims can exist in conjunction with the *Wellcome* decision, without violating any prohibition on claims to methods of medical treatment.

Gault J delivered the judgment of the Court of Appeal. His Honour recognized that in claims to medically related inventions, such as the pharmaceutical compositions or compounds in pharmaceutically pure forms, inventiveness actually lies in the medical use, notwithstanding that the new use does not form part of the claim. The novelty in such claims is considered to lie in the fact that the pharmaceutical composition is new, though the truly inventive step is in the discovery of the new use.<sup>92</sup> The Court noted that to claim the compound or the composition as 'pharmaceutical' is, in effect, to claim by reference to the purpose for which the compound or composition is to be used and rests on the inventiveness of the use. Consequently, when claimed in this form, it could be said that the novelty resides in the intended use.<sup>93</sup> After consideration of the 'analogy' approach taken in the *Eisai* case, the Court stated that the step necessary to render Swiss-type claims acceptable would be to recognize that novelty as well as inventiveness resided in the newly discovered *purpose* for which the medicament was to be used.<sup>94</sup>

After reviewing the UK cases of *Wyeth* and *Schering* and *Bristol-Myers Squibb* the court concluded that it had not been persuaded that there was anything in the NZ Act or in New Zealand case law that directly precluded a similar process of reasoning to that adopted in the *Eisai* case. The court also rejected the proposition that the European basis for finding novelty in a Swiss-type claim differed significantly from the provisions in the New Zealand legislation.

The Court accepted that:

- claims to methods of medical treatment were precluded;
- new methods of treatment of the human body were recognized as inventions and might be claimed except in areas of surgery, therapy and diagnosis; and
- product claims for the first therapeutic use were allowed.<sup>95</sup>

---

<sup>91</sup> Ibid, [18].

<sup>92</sup> Ibid, [30].

<sup>93</sup> Ibid, [31].

<sup>94</sup> Ibid, [38].

<sup>95</sup> Ibid, [52].

The key difference between New Zealand and European law, however, related to the question of where novelty was perceived to reside. The Court explained that under Art 54(5) novelty might be found in the *new use*. Under the New Zealand practice, on the other hand, novelty could be found in the *product formulation*. However, the court's view was that this distinction seemed blurred where first pharmaceutical use claims were permitted in forms such as 'a pharmaceutical composition [of the known compound]' or 'a pharmaceutical pure form [of the known compound]' that really focuses on the new use.<sup>96</sup>

In its conclusion, the court emphasised that by its accession to the Agreement on Trade-related Aspects of Intellectual Property Rights (*TRIPS*),<sup>97</sup> New Zealand had undertaken to make available patents 'for any inventions, whether products or processes, in all fields of technology, provided they are new, involve an inventive step and are capable of industrial application'.<sup>98</sup> Thus, once it was accepted that there could be new invention in the discovery of previously unknown properties in a compound, the obligation to make patent protection available applied. For these reasons, the court concluded that the provisions of the NZ Act should, if possible, be construed so as to give effect to TRIPS, and held that Swiss-type claims were valid in New Zealand.<sup>99</sup>

The Court of Appeal also discussed the issue of patentability of methods of medical treatment. It is noteworthy to list the following points made by the court in this regard.

- It could no longer be said that a method of medical treatment should not be an invention.<sup>100</sup> The Court departed from the view adopted in *Wellcome* and agreed on this point with the view adopted by the Australian Federal Court in *Bristol-Myers Squibb Co v F H Faulding & Co Ltd*.<sup>101</sup>
- The exclusion from patentability of such methods rests on public policy or moral grounds.<sup>102</sup>

---

<sup>96</sup> Ibid, [53].

<sup>97</sup> *Agreement on Trade-Related Aspects of Intellectual Property Rights Including Trade in Counterfeit Goods* (1994) 25 IIC 209 (TRIPS).

<sup>98</sup> TRIPS, Art 27:3.

<sup>99</sup> *Pharmaceutical Management Agency Ltd v Commissioner of Patents* [1999] NZCA 330, [64] and [65].

<sup>100</sup> Ibid, [26].

<sup>101</sup> [2000] FCA 316.

<sup>102</sup> *Pharmaceutical Management Agency Ltd v Commissioner of Patents* [1999] NZCA 330 at [29].

- It is doubtful whether the exclusion of inventions, which are 'generally inconvenient', remains part of the law of New Zealand, since the s 17 of the NZ Act expressly deals with inventions which are contrary to law or morality.<sup>103</sup>
- It would be logical to permit claims to extend to the methods of medical treatment of human beings but to require from the patentee a disclaimer of any right to sue the medical practitioner.<sup>104</sup> This approach is very similar to one adopted by amendment to 35 US Constitution, paragraph 287(c).

*Pharmaceutical Management Agency* is important case because firstly, it put New Zealand patent law in line with European patent law with regard to second therapeutic use claims. Secondly, this decision is the first common law appellate level review of the validity of Swiss-type claims.<sup>105</sup> The court provided a well-reasoned basis for development by 'analogy' with existing law and reached a fully reasoned conclusion that such claims are allowed in New Zealand. Thirdly, the court also provided well-reasoned findings mentioned above in relation to methods of medical treatment, though it did not go so far as to say that patents must be granted for such methods.

One further point needs to be made about the patent in issue in the *Wellcome* case. Since the invention concerned an unexpected discovery that a previously known compound was effective in another therapeutic treatment, it could be viewed as a 'second therapeutic use' claim and, subsequent to *Pharmaceutical Management Agency*, it would allowable in New Zealand. The point is that if at the time of the *Wellcome* case decision this type of claim was allowable, and the claim was drafted in the Swiss-type format, Wellcome Foundation Ltd could have been granted a patent.

#### 3.4.3.2 *Pfizer Inc v Commissioner of Patents*<sup>106</sup> (Pfizer)

In this case, the appellant, Pfizer Inc, appealed from judgment of Ellis J in the High Court.<sup>107</sup> Ellis J had upheld the decision of the Assistant Commissioner of Patents to refuse patents to Pfizer Inc for methods of medical treatment of psychotic

<sup>103</sup> Ibid at [20]. Section 17 prohibits patents where 'the use of the invention in respect of which the application is made would be contrary to morality'.

<sup>104</sup> *Pharmaceutical Management Agency Ltd v Commissioner of Patents* [1999] NZCA 330, [65].

<sup>105</sup> G Arthur, 'Swiss Type Claims Held Valid in New Zealand' (2000) 20(8) *European Intellectual Property Review*, 380, 384; Michael Hawkins, 'Swiss' Type Patent Claims on Hold' (1997) 9 *Patent World*, 8.

<sup>106</sup> [2004] NZCA 104.

<sup>107</sup> *Re Pfizer Inc*, HC WN AP257/2000 20 August 2002.



disorders using a new compound. His Honour held that such applications must be denied patenting based on the policy grounds located in the proviso to s 6 of the *Statute of Monopolies* that the invention must not be 'generally inconvenient'.<sup>108</sup>

On appeal Pfizer Inc argued that further to the Australian decisions in *NRDC* and *Joos*, and the New Zealand decisions in *Wellcome* and *Pharmaceutical Management Agency*, there was no longer any basis for methods of medical treatment exclusions; and that it was doubtful whether the Commissioner could refuse an application under the 'general inconvenient' proviso to s 6 of the *Statute of Monopolies*.<sup>109</sup>

In dismissing the appeal, Court of Appeal<sup>110</sup> held unanimously that although methods of medical treatment might be inventions, based on 'longstanding authority', it would be generally inconvenient to protect them with letters patent.<sup>111</sup> The Court also concluded that neither *Pharmaceutical Management Agency* nor *Pfizer* overruled *Wellcome* in relation to patenting of medical methods. The Court recognised that interpretation of meaning of 'invention' in s 2 of the NZ Act involves 'an unusually complex exercise, because of the drafting of incorporating, by reference, s 6 of the *Statute of Monopolies*, rather than expressing Parliament's intention in contemporary language'.<sup>112</sup> This, the Court explained, had led to judicial interpretation of the archaic words of s 6 in a contemporary context. That, in turn, had led to the judicial pronouncements on s 6 rather than on the archaic words of the section itself.<sup>113</sup>

In relation to the interpretation of "generally inconvenient" in s 6, the Court stated the following:

The importance of case law in this area results from the flexibility that has, of necessity, been introduced into the exercise of statutory interpretation in this area of the law to accommodate the archaic language of s 6 of the *Statute of Monopolies*. But the process is still a process of statutory interpretation, to determine the scope of the

---

<sup>108</sup> *Pfizer Inc v Commissioner of Patents* [2004] NZCA 104, [26].

<sup>109</sup> *Ibid*, [36].

<sup>110</sup> Anderson P, Glazebrook, Young, O'Regan and Hammond JJ.

<sup>111</sup> *Pfizer Inc v Commissioner of Patents* [2004] NZCA 104, [7].

<sup>112</sup> *Ibid*, [61].

<sup>113</sup> *Ibid*, [61]. The author disagrees with this approach and argues in Chapter 5 that the judicial interpretation of words in the proviso to s 6 of the *Statute of Monopolies* by modern courts does not correspond with the original meaning of those words. The author further argues in Chapters 5 and 6 that courts should not simply make pronouncements on archaic sections. Instead, the courts must interpret the words in accordance with their original intended meaning, text and purpose.

definition and the extent of patentability permitted under it. In our view the medical treatment exclusion does have a statutory base....<sup>114</sup>

On the basis of this interpretation of the proviso to s 6, the Court pronounced that in New Zealand patents to methods of medical treatments would be against public policy and thus, generally inconvenient.<sup>115</sup>

#### **3.4.4 Summary of Position in New Zealand**

There is yet no express exclusion of methods of medical treatment from patentability, and the issue has been dealt with by the courts. This position, until the NZ Act is amended, will remain similar to that of Canada and different to that of UK and Europe. Following *Pfizer*, although methods of medical treatment might be considered to be inventions in New Zealand, it would be generally inconvenient to grant them letters patents.<sup>116</sup> Nevertheless, although pure methods of medical treatment are not directly patentable in NZ, such methods can be patented indirectly by using the Swiss-type claims.

Following the cases discussed above, claims to treatment would be allowed in New Zealand in the following circumstances:

- in the situation when the human does not require medical assistance or professional medical skill;
- in the cases of baldness, precocity, infertility, obesity, skin atrophy, ageing, fertilization, dryness or oiliness of skin;
- in the case of reducing desire of smoke, methods of contraception;
- for diagnostic testing not requiring surgery;
- for inhibiting toxic shock syndrome;
- for the treatment of lice on the body;
- for the treatment of teeth; and

---

<sup>114</sup> *Pfizer Inc v Commissioner of Patents* [2004] NZCA 104, [64].

<sup>115</sup> *Ibid*, [63].

<sup>116</sup> *Ibid*, [7].

- in the case of improving health and hygiene by the products that might be found on health counters in supermarkets, including herbal remedies, vitamins,<sup>117</sup> as these do not require involvement of professional medical skill.

Accordingly, the position of New Zealand Patent Office regarding treatment of human beings is broader than that adopted by the European Patent Office or the UK Patent Office, in that in some circumstances the claims to treatment would be allowed in New Zealand.

### 3.5 THE UNITED STATES

#### 3.5.1 Relevant Statutory Provisions

Like the patent systems of the UK, Australia, New Zealand and Israel, the US patent system derived from early English law, which originated from Letters Patent and the *Statute of Monopolies*. Though current US patent law is not identical to the current legislation in Australia, it nevertheless can provide useful directions or alternatives for solving the debate concerning patentability of medical treatments.

After the US gained independence from Britain, each of the states retained the authority to issue patents.<sup>118</sup> However, since enactment of the US Constitution in 1781, which empowered the federal government with the authority to grant patents, the states have not issued patents.<sup>119</sup>

There are essentially three levels of American patent law: the US Constitution, which grants an authority for Congress to create patent legislation;<sup>120</sup> the Congressional legislation;<sup>121</sup> and the interpretive case law. The Constitution provides that Congress shall have the power '[t]o Promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writing and Discoveries.'<sup>122</sup> In accordance with this provision, Congress enacted the first patent statute, the *Patent Act* of 1790 (the **1790 US Act**), which together with the case law, set out the standards for American patent law.

<sup>117</sup> *Pharmaceutical Management Agency Ltd v Commissioner of Patents* [1999] NZCA 332.

<sup>118</sup> *The Encyclopedia of Patent Practice and Invention Management* edited by R Calvert (1964) 384, 393-94.

<sup>119</sup> *Ibid*, 396-97.

<sup>120</sup> See US Constitution, Art I, Para 8, cl.8.

<sup>121</sup> See generally 35 US Code (1994).

<sup>122</sup> US Constitution, Art I, Para 8, cl.8.

Since the 1790 US Act, there have been four major revisions, the most recent in 1952, when Congress replaced the word 'art' in the definition of invention patentable with the word 'process'. Title 35 US Code §101 (1994) defines 'inventions patentable' as:

[a]ny new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title.

Title 35 US Code §100(b) (1994) defines the term 'process' as follows:

The term process means process, art, or method, and includes a new use of a known process, machine, manufacture, composition of matter, or material.

Under this broad definition, almost any process, machine, manufactured art, or chemical compound would appear to be patentable.<sup>123</sup> Since the statutory limitation of the scope of patentable subject matter is flexible, it appears that methods of medical treatment are covered by the definition of the 'inventions patentable' contained in § 101. Therefore, the present interpretation of § 101 allows patentability of methods of medical treatment in the US. However, as early law indicates, this was not always so.

### **3.5.2 Early Case Law and Legislation**

#### **3.5.2.1 The Vulcanized Rubber Story**

The earliest historical evidence regarding patenting of medical inventions in the US was the dramatic case involving a medical breakthrough in dentistry in 1844. Charles Goodyear discovered a method of vulcanizing rubber to make it hard and durable. One of the uses of this technology was to make denture material. After realizing the possible commercial applications of this promising technology, the Goodyear Company patented the method of using vulcanized rubber to make dentures.<sup>124</sup>

The Company then devised a system to extract patent royalties from the dental profession for every denture made. Since the discovery was soon widely adopted

---

<sup>123</sup> Steven Nichols, 'Comment: Hippocrates, The Patent-Holder: The Unenforceability Of Medical Procedure Patents' (1997) 5 *George Mason Law Review* 227, 234.

<sup>124</sup> Malvin Ring, 'The Rubber Denture Murder Case: The True Story of the Vulcanite Litigations' (1984) 32 *Bull of the History of Dentistry* 1, 3-4.

by dentists, in the 1860s the Company began filing a series of infringement lawsuits against dentists across the country seeking royalties for Goodyear. Josiah Bacon, the Treasurer of the Goodyear Dental Vulcanite Company, for many years successfully prosecuted the infringement cases.<sup>125</sup>

The litigation led to considerable opposition from the dental profession. One particularly frustrated dentist, Dr Samuel Chalfant, even choose to move his practice across the country to avoid paying royalties for the patent. Finally, the Vulcanite litigations were dramatically terminated in 1879, when Dr Chalfant pursued Mr Bacon to a hotel in San Francisco and shot him dead.<sup>126</sup>

The vulcanized rubber story concerned a patent for a substance, device and the method of making it. Clearly, it was not a method of medical treatment. However, this story illustrates that a combination of patents and human health can produce emotive responses.<sup>127</sup>

### 3.5.2.2 *Morton v New York Eye Infirmary*<sup>128</sup>

Methods of medical treatment were first patented in the US in the beginning of the nineteenth century. One of the first patents involving a medical procedure dates back to 1846, and concerned a use of ether as an anesthetic: *Morton v New York Eye Infirmary*<sup>129</sup> (**Morton**).

In 1846 Morton obtained a patent for a procedure of administering ether to surgical patients as an anesthetic. In 1862 Morton sought to recover damages for infringement of his patent by *New York Eye Infirmary*. New York Circuit Court invalidated the patent based on the following reasons. The existence of ether's intoxicating effect on animals was well known to chemists, and so the origin and existence of ether formed no part of the discovery. The discovery was in the fact that inhalation of increased quantities of ether caused a state of complete insensibility to pain. This effect 'alone was new and to that only [could] the term 'discovery' apply'.<sup>130</sup> On this basis, the court determined that the patent was not valid.

---

<sup>125</sup> Ring, above n 110, 5

<sup>126</sup> Ring, above n 110, 16.

<sup>127</sup> Noonan, above n 101, 653.

<sup>128</sup> 17 F. Cas. 879 (C.C.S.D.N.Y. 1862).

<sup>129</sup> *Morton v New York Eye Infirmary* 17 F. Cas. 879 (C.C.S.D.N.Y. 1862).

<sup>130</sup> *Ibid*, 882.

The court concluded that such discoveries were patentable only in combination with a means of operation or other type of embodiment for utilizing the new effect.<sup>131</sup> However, 'the natural functions of an animal', such as inhaling, could not constitute any part of this requisite combination.<sup>132</sup>

The rationale of the case is far from clear. Nonetheless, *Morton* had a substantial impact on patentability of methods of medical treatment. Mistakenly, the phrase 'the natural functions of an animal'<sup>133</sup> was interpreted as prohibiting patents for all methods of medical treatment. A careful reading of the case reveals no such prohibition. Clearly, the patent in *Morton* was invalidated for technical reasons, and not for a lack of the patentable subject matter. Many authors argue that it could not stand as authority for exclusion of methods of medical treatment in the US.<sup>134</sup>

### 3.5.2.3 *Ex Parte Brinkerhoff*<sup>135</sup>

Some twenty years after the *Morton* case, the Patent Office Board of Appeals in *Ex Parte Brinkerhoff* (*Brinkerhoff*) relied on that case to affirm the refusal by the Patent Office of a patent for a method of treating hemorrhoids by injecting already patented medication into them. The Commissioner of Patents interpreted *Morton* as prohibiting patenting medical methods, and stated that 'methods or modes of treating... diseases are not patentable.' However, the rationale for this decision was neither ethical considerations nor the fact that the alleged invention was a method of medical treatment. Rather, it was the *uncertainty of the result* of the medical method. The Commissioner stated that the medical treatment was so uncertain and its results so speculative that patenting of such a method would mislead the public into believing the method would produce the desired result in all cases.<sup>136</sup>

Thus, the uncertainty of results was the only specific reason for the prohibition of the patent claimed. This does not appear to be a valid reason for categorically refusing *all* methods. This is the question of utility, which is one of the requirements of 35 US Code § 101, which requires that an invention achieve its purpose. It is submitted that the inclusion of this utility requirement in US patent legislation completely removes the rationale for refusing patents for methods of medical

---

<sup>131</sup> Ibid, 884.

<sup>132</sup> Ibid.

<sup>133</sup> Ibid.

<sup>134</sup> Beata Gocyk –Farber, 'Note, Patenting Medical Procedures: A Search for a Compromise Between Ethics and Economics' (1997) 18 *Cardozo Law Review* 1527, 1535; Noonan, above n 101, 654.

<sup>135</sup> 24 Comm'r Dec. 349, (1883) 27 *Journal of the Patent and Trademark Office Society* 797; 146 US 515 (1892).

<sup>136</sup> *Ex Parte Brinkerhoff*, (1883) 27 *Journal of the Patent and Trademark Office Society* 797, 798.

treatment as expressed in *Brinkerhoff*. Moreover, this rationale proved to be unworkable in the second half of the twentieth century due to the rapid development of medical science and the considerable increase in the cost of the research. To ensure fast progress in medicine, patent protection was an essential condition of the funding of medical research.<sup>137</sup> Thus, even though inventions of this nature might not provide certainty in their results, they were still granted patent protection for these reasons.

#### 3.5.2.4 57<sup>th</sup> Congress in 1902 and 58<sup>th</sup> in 1903

The controversy concerning methods of medical treatment brought about by the Goodyear Company litigation and the uncertainty of the rationale in *Morton* led to the introduction Bill HR 12451 into 57th Congress in 1902, which proposed to exclude medical and surgical methods from the field of patentable subject matter.<sup>138</sup> Bill 12451 sought to relieve medical and dental practitioners from 'unjust burdens imposed by patentees holding patents covering methods and devices for treating human diseases...'.<sup>139</sup>

Before failing in Congress, the Bill was approved by 38 state dental associations. If passed, the Bill would have allowed qualified dentists to perform operations 'free of royalties for the benefit of society'.<sup>140</sup> A House Committee on Patents submitted to the House of Representatives a Report where it did not approve the proposition against patents. Even though the Committee Report concluded that it had been the practice of the Patent Office to grant such patents, it emphasized that the law about patenting of methods of medical treatment was unsettled, and therefore required clarification.<sup>141</sup>

The Bill, however, never reached a floor vote, and no action was taken by Congress to enact this legislation. After failures in 1902 and 1903, Congress lost interest in excluding medical procedures from statutory subject matter.<sup>142</sup> Notwithstanding this failure, the 1902 Bill played an important role some 90 years later when, in 1994, modern proponents introduced a new amendment to the patent legislation.<sup>143</sup> Many of the objections cited by the Committee in support of the 1902 Bill were reviewed and cited in 1994 by the proponents in support of the

<sup>137</sup> William Noonan, 'Patenting Medical Technology' (1990) 11 *The Journal of Legal Medicine* 263, 268.

<sup>138</sup> H.R. 12451, March 12, 1902.

<sup>139</sup> *Ibid*, 17.

<sup>140</sup> *Ibid*, 1.

<sup>141</sup> Noonan, above n 101, 654.

<sup>142</sup> See Howard Forman, *Law of Chemical, Metallurgical and Pharmaceutical Patents* 64-71 (1967), cited in Noonan, above n 101, 654.

<sup>143</sup> Public Law No 104-208, Section 287(c).

amended legislation. Thus, it could be said that the early controversy was never resolved but shelved for some time.

### 3.5.2.5 The Situation After the 1902 and 1903 Bills

Congress inaction in 1902 and 1903 was interpreted by the Patent Office as a sign that it could properly issue patents on medical methods.<sup>144</sup> Consequently, despite the ruling in *Brinkerhoff*, the Patent Office frequently issued patents on therapeutic methods during the following fifty years.<sup>145</sup>

Moreover, development of the pharmaceutical industry and medical research progressed very quickly during World War I. World War II gave medical research even greater priority, since researchers discovered new processes for mass producing penicillin, synthetic quinine substitutes and gamma globulins.<sup>146</sup> By 1950 medical research had become enormously expensive and required adequate protection. The American Medical Association (**AMA**) acknowledged this, and in 1948 its Judicial Council issued an Official Opinion stating that it did not consider medical process patents unethical. It stated that '[o]ur law governing patents are based on the sound doctrine that one is entitled to protect his discovery.'<sup>147</sup> A few years later, in 1952, patent law was codified as Title 35 of the US Code and two years after that the Patent Office overruled *Brinkerhoff* in *Ex Parte Scherer*.<sup>148</sup>

### 3.5.2.6 *Ex Parte Scherer*<sup>149</sup>

This landmark case was a significant breakthrough in the field of patentability of medical inventions. The Board of Patent Appeals in *Ex Parte Scherer* (**Scherer**) expressly rejected *Brinkerhoff* and ruled that medical processes were patentable subject matter.<sup>150</sup> Since then, methods or processes of medical treatment have been patentable in the US.

In this case, Scherer applied for a patent for surgical methods of injecting fluid into the human body through the epidermis by a pressure jet instead of a hypodermic

---

<sup>144</sup> Noonan, above n 101, 654.

<sup>145</sup> See, eg, *Ex Parte Wappler*, 26 U.S.P.Q. 191 (Pat. Off. Bd. App. 1935); *Ex Parte Kettering*, 35, U.S.P.Q. 342 (Pat. Off. Bd. App. 1936).

<sup>146</sup> P. Starr, 'The Social Transformation of American Medicine' (1982), 340-341, cited Noonan, above n 123, 268.

<sup>147</sup> Official Opinion of the Judicial Council, 163 JAMA 1156, 1157.

<sup>148</sup> 103 U.S.P.Q. 107 (Pat. Off. Bd. App. 1954).

<sup>149</sup> *Ibid.*

<sup>150</sup> *Ibid.*, 110.



needle.<sup>151</sup> The accurate 'placing of the fixed quantity of medicament at a predetermined position beneath' the skin layer was the claimed result. The applicant argued that this result was 'useful' within the statute. The examiner, as required under *Brinkerhoff*, refused the application. The Patent Office concluded that the only useful result of the claimed method was a change in the human body through its reaction to the medicine. This result was not dependent on the methods by which the medicine was injected.<sup>152</sup>

Taking into account the importance of the issues raised by the claim, the appeal was heard by an expanded panel of the Board. The Board found that the claimed method had utility and held that 'it cannot be categorically stated that all such methods are unpatentable subject matter merely because they involve some treatment of the human body.'<sup>153</sup> The Board stated that there was nothing in the patent statute that categorically excluded such methods, nor had any general rule of exclusion been developed by decisions. It distinguished *Morton* on the grounds that *Morton* may be read to be a patentability rejection due to lack of novelty or obviousness.<sup>154</sup>

The significance of *Scherer* is that it reversed a 150-year-old prohibition of methods of medical treatment patents in the US. It established the validity of medical procedure patents. Since then the Patent Office has issued many patents protecting the inventions of surgical and therapeutic procedures.<sup>155</sup> However, the controversy surrounding patenting of methods of medical treatment was far from over. Opponents of such patenting viewed *Scherer* only as a decision within the Patent Office and preferred to rely on the court decision in *Martin v Wyeth*<sup>156</sup> (*Martin*).<sup>157</sup> In *Martin* a District Court invalidated a claim for a method of treating mastitis in cows. Although the court raised ethical issues about the patenting of medical methods, it did not base its rejection on ethical grounds. It invalidated the claims because they constituted 'merely the application of an old and well-known device to a new use.'<sup>158</sup>

---

<sup>151</sup> *Ex Parte Scherer* 103 U.S.P.Q. 107 (Pat. Off. Bd. App. 1954).

<sup>152</sup> *Ibid*, 109.

<sup>153</sup> *Ibid*.

<sup>154</sup> *Ibid*, 109-110.

<sup>155</sup> Noonan, above n 101, 658-60, Table 1. Noonan provides a very useful table with examples of medical process patents granted from 1862 to 1995.

<sup>156</sup> 96 F. Supp. 689, *aff'd*, 193 F. 2d 58 (4<sup>th</sup> Cir. 1951).

<sup>157</sup> See *Chemetron Corp. v Airco Inc.*, 198 U.S.P.Q. (BNA) 119 (N.D.Ill. 1976), where the Court raised the question whether medical processes should be patentable.

<sup>158</sup> *T. Martin v Wyeth* 96 F. Supp. 689, *aff'd*, 193 F. 2d 58 (4<sup>th</sup> Cir. 1951), 695.

However, the AMA itself was more willing to accept the patentability of methods of medical treatment following the decision in *Scherer*. In 1955, only one year after *Scherer*, the AMA again acknowledged that medical research expenses justified the patenting of medical procedures, and concluded that it would be ethical for a physician 'to patent surgical instruments, appliances and medicines, or copyright publications, methods, and procedures.'<sup>159</sup>

### 3.5.3 The Pallin Patent and its Consequences

#### 3.5.3.1 *Pallin v Singer*<sup>160</sup>

In the 1990s, the situation regarding patenting of medical treatments in the US began to change. The medical professional associations led the revolution by arguing strongly against medical procedure patents.<sup>161</sup> One reason for the controversy was a patent infringement lawsuit filed by Dr Samuel Pallin, an ophthalmologist from Arizona. Unintentionally Dr.Pallin provoked one of the most emotional patent debates in American history,<sup>162</sup> and the case soon invoked a legislative response resulting in a substantial reduction in remedies available for physicians whose medical methods patents were infringed.

*Pallin v Singer* was the first known lawsuit to enforce a medical procedure patent. In 1990 Dr Pallin made an upside-down V-shaped incision in a patient's eye while removing a cataract. Due to the patient's heart condition, Dr Pallin did not stitch the incision after surgery. Two weeks later, he unexpectedly discovered that the scar had healed without a suture and had far less scar tissue than a normal sutured incision.<sup>163</sup> Traditionally, the incision was closed by sutures to prevent wound separation. However, this often led to astigmatism.<sup>164</sup>

Dr Pallin submitted an article describing his findings in a leading medical journal, the *Journal of Cataract and Refractive Surgery*. The Journal rejected the submissions on the ground that Pallin's findings offered no true innovation.<sup>165</sup> To

---

<sup>159</sup> AMA Principles of Medical Ethics 11-12, Para.7 (1955).

<sup>160</sup> 36 U.S.P.Q. 2d (BNA) 1050 (D. Vt. 1995).

<sup>161</sup> Scott Anderson, 'A Right Without a Remedy: The Unenforceable Medical procedure Patent' (1999) 3 *Marquette Intellectual Property Law Review* 117, 125.

<sup>162</sup> Gocyk -Farber, above n 120, 1527.

<sup>163</sup> Jodie Snyder, 'A Patent for a Eye Surgery? Court Case Arises Over the Technique' *The Phoenix Gazette*, Apr. 4, 1995, A1, cited by Joseph Reisman, 'Physicians and Surgeons as Inventors: Reconciling Medical Process Patents and Medical Ethics' (1995) 10 *High Technology Law Journal* 355, 366.

<sup>164</sup> *Pallin v Singer* 36 U.S.P.Q. 2d (BNA), 1050.

<sup>165</sup> See Hearings on H.R. 1127 before the Subcomm. On Courts and Intellectual Property of the House Comm. On the Judiciary, 104<sup>th</sup> Cong. 1<sup>st</sup> Sess (1995), 4 (testimony of Dr Samuel Lear Pallin) (Hearings).

be recognized in his profession, Dr Pallin then turned to the US Patent Office to document his discovery. In 1992 Dr Pallin was granted a patent for 'Method of Making Self-Sealing Episcleral Incision.' Then, he offered to donate the patent to a national cataract surgeons group, but that offer was also rejected. Finally, since the Pallin patent resulted in a saving of \$17 per operation, Dr Pallin offered a minimal royalty of \$4-5 for the procedure.<sup>166</sup> Although very few surgeons had been willing to pay the royalty (notwithstanding a \$17 saving), the technique became very popular.

In 1994 Dr Pallin sued several of his peers, including fellow eye surgeon, Dr Jack Singer, for the infringement of his patent. Dr Pallin alleged that Dr Singer not only used his patent incisions, but induced others to infringe the patent by publishing an article in a medical journal about the surgical technique with instructions of how to use the procedure.<sup>167</sup> Despite the savings that resulted from the invention, the defendants objected to paying either the patent royalty fee per operation or a flat fee for a clinic of \$2,500 to \$10,000 per year.<sup>168</sup> In the court proceeding, Dr Singer and others motioned for a summary judgment due to invalidity of the patent.<sup>169</sup> The defendants asserted that Pallin's chevron cut was not new and it was obvious to other eye surgeons. However, the court found that the defendants failed to demonstrate invalidity of the patent and denied the motion.

Yet the defendants ultimately prevailed, as a federal district judge entered a consent order, effectively decreeing Pallin's patent invalid. This consent order finally resolved the case. Dr Pallin agreed to dismiss his suit after a two day hearing in the court.<sup>170</sup>

*Pallin v Singer* received widespread attention from the media, professional associations, academia and politicians.<sup>171</sup> Physicians across the country expressed strong opposition to medical process patents, calling them 'horrendous' and warning that if Dr Pallin won, the victory might have 'profoundly devastating and mind-boggling consequences' for medicine.<sup>172</sup> In response to this opposition, in

---

<sup>166</sup> Medical Procedures Act of 1995: Hearings on H.R. 1127 before the Subcomm. On Courts and Intellectual Property of the House Comm. On the Judiciary, 104<sup>th</sup> Cong. 39, 41 (1995) (Medical Hearing), 4, Hearings, above n 151.

<sup>167</sup> Lee Bowman, 'Physicians Stake Claims to their Art of Healing; Courts will rule on Patents, While Medical Societies Denounce Them as Unethical, Harmful, S.F. Exam' (1995) July 16, B-1.

<sup>168</sup> See Hearing on H.R. 1127 before the Subcomm. On Courts and Intellectual Property of the House Comm. On the Judiciary, 7.

<sup>169</sup> *Pallin v Singer* 36 U.S.P.Q. 2d (BNA) 1050, 1051.

<sup>170</sup> See Medical Procedure Patent Claims Are Invalidated in Consent Judgment, (1996) 51 *Patent Trademark and Copyright*, April 11, 688.

<sup>171</sup> Scott Anderson, above n 147, 118.

<sup>172</sup> Gocyk-Farber, above n 120.

1994 the AMA reversed its position, stating that medical process patents are per se unethical,<sup>173</sup> and promised to 'work with Congress to outlaw this practice'.<sup>174</sup>

### 3.5.3.2 Attempts to change US law following *Pallin v Singer*

The effective lobbying by the AMA influenced members of Congress to propose a Bill seeking to prohibit the patenting of medical processes. In March 1995, a new Bill, *The Medical Procedures and Affordability Act*, House Bill 1127, was introduced. The Bill proposed to prohibit the issuance of patents 'for any invention or discovery of a technique, method or process for performing a surgical or medical procedure, administering a surgical or medical therapy or making a medical diagnosis'.<sup>175</sup>

Opponents of the Bill criticised it as being too broad and vague. The Clinton administration testified that excluding surgical and medical procedures from patentability was not the proper way to address the concerns surrounding medical patents.<sup>176</sup> Also, the Executive Director of the American Intellectual Property Law Association, Dr Michael K. Kirk, opposed the Bill arguing that it would undesirably remove patent incentives and create an undesirable international precedent. He stated that the 'underlying concepts of [House Bill 1127] is so failing in merit that all of the technical problems are not worth addressing', and concluded that 'the need for this legislation has not been established'.<sup>177</sup>

In response to the criticism of House Bill 1127, Representative Ganske offered a modified version as an amendment, House Bill 3814.<sup>178</sup> This Bill passed the House, but was not passed by the Senate. In the alternative, Senator Bill Frist of Tennessee, a thoracic surgeon, introduced Senate Bill 1334,<sup>179</sup> which did not pass either. Senator Frist then introduced a further Bill, Senate Bill 2105,<sup>180</sup> which likewise was unsuccessful.

---

<sup>173</sup> Sabra Chartrand, 'Why Is This Surgeon Suing? Doctors Split Over Patenting of Their Techniques' (1995) *New York Times*, June 8, D1, D5.

<sup>174</sup> The War Over Patents, *Argus*, July, 1994, 8, cited by Gocyk –Farber, above n 120.

<sup>175</sup> H.R. 1127, 104<sup>th</sup> Congress (1995).

<sup>176</sup> Hearing on H.R. 1127, Statement of G. Lee Skillington, Counsel, Office of Legislative and International Affairs, US Patent and Trademark Office.

<sup>177</sup> Hearing on H.R. 1127, Statement of Dr Kirk.

<sup>178</sup> H.R. 3814, 104<sup>th</sup> Congress (1996).

<sup>179</sup> S. 1334, 104<sup>th</sup> Congress (1995).

<sup>180</sup> *Ibid*.

### 3.5.3.3 Current legislation - 35 US Code § 287 (c)

Although Senate Bill 2105 never passed into law, a substantial portion of it became incorporated into § 616 of 35 US Code, which provides that § 287 is amended by adding at the end a new sub-§ (c). In less than one week, on September 30, the Senate passed House Bill 4278, which was signed by the President Clinton, creating an amendment to 35 US Code § 287 (c) (**Public Law 104-208**).

§ 616 provides that § 287 is amended as follows:

(c)(1) With respect to a medical practitioner's performance of a *medical activity that constitutes an infringement* under s 271(a) or (b) of this title, the provisions of ss 281, 283, 284, and 285 of this title *shall not apply against the medical practitioner or against a related health care entity with respect to such medical activity*.

(2) For the purpose of this subs:

(A) the term 'medical activity' means the performance of a medical or surgical procedure on a body, but shall *not* include

- (i) the use of a patented machine, manufacture, or composition of matter in violation of such a patent,
- (ii) the practice of a patented use of a composition of matter in violation of such patent, or
- (iii) the practice of a process in violation of a biotechnology patent.

*(Emphasis added)*

The new law applies only to 'medical activities', not to drugs or devices, since it makes a clear distinction between patents for medical procedures on one hand, and compositions/drugs and machine/devices on the other. Therefore, patents on medical and surgical procedures are unenforceable against medical practitioners and related health care entities, unless they fall under one of three exceptions (§ 616(c)(2)(A)(i-iii)).

Public Law 104-208 allows a physician to enforce a patent for a medical or surgical procedure provided that the infringer's activity also infringes an unexpired patent for a medical machine/device, composition/drug or method of their use. Accordingly, there remains a fair amount of latitude for a physician to enforce patents involving methods of medical treatment. Alternatively, a patent for a medical or surgical procedure using a device, drug or method of their use, would

not be enforceable if such device, drug or method of their use are not patented or their patent is already expired.

The main effect of the new law is that it gives medical practitioners and related health care entities a statutory exemption from liability for infringement of medical procedure patents. Thus, although the Patent Office will grant a patent for medical procedure, such patent will be unenforceable against these users.<sup>181</sup> It means that the patent owner is deprived of the right to sue for damages or seek injunctive relief when licensed medical practitioners engaging in medical activities infringe the patents.<sup>182</sup> This transforms medical method patents into '...a rather expensive certificate of merit'<sup>183</sup> and makes them meaningless. Therefore, the suggestion is that the new law can be seen as an equivalent to a prohibition on medical process patents.

Some commentators have argued that the way in which the Public Law 104-208 became law undermines its legitimacy.<sup>184</sup> The reasons for this is that neither House Bill 1127 nor Senate Bill 1334 appeared close to becoming law 'until § 616 was slipped' into an appropriations bill during the closing days of the 104<sup>th</sup> Congress.<sup>185</sup> Normally, before a Bill becomes law, it will be debated in one or more Congressional committees. By adding the amendment to an Appropriations Bill it 'by-passed' the usual committee hearings.<sup>186</sup> Thus, the new law came into existence 'by-passing the legislative channels such laws usually go through'.<sup>187</sup>

Since the law was passed as an amendment to an Appropriations Bill, it is argued that it was valid for only one year.<sup>188</sup> Yet, the law still continues to be in the statute. Also, § 616 became a subject of criticism led by Senator Orin Hatch, Chairman of the Senate Judiciary Committee, who expressed concern that § 616 was bad policy and a possible violation of US obligations under international treaty.<sup>189</sup>

---

<sup>181</sup> United States Patent and Trademark Office, 'Utility Examination Guidelines' (2001) 66 *FR* 1092.

<sup>182</sup> See § 616 (c)(1).

<sup>183</sup> Michael Garvey, 'New Medical-Procedure Patents Can't Be Infringed' (1996) *The IP Strategist* 5.

<sup>184</sup> Nichols, above n 109, 229; Martin, above n 34, 402 and 406.

<sup>185</sup> Nichols, above n 109, 229.

<sup>186</sup> Bradley Meier, 'The New Patent Infringement Liability Exception For Medical Procedures' (1997) 23, *Journal of Legislation* 265, 275.

<sup>187</sup> Martin, above n 34, 402.

<sup>188</sup> Linda Judge, 'Issues Surrounding the Patenting of Medical Procedures' (1997) 13 *Computer & High Technology Law Journal* 181, 190.

<sup>189</sup> Bill with PTO Funding and Patent Reform on Medical Procedures is Signed into Law, 52 *Patents, Trademark & Copyright Journal* 597, 597 (BNA 1996).

### 3.5.4 Summary of US Position

As in the UK, the controversy about patenting of medical inventions in the US is longstanding. However, in contrast to the UK and other reviewed countries, the law of the US regarding the patentability of such inventions is very liberal. Indeed, the US Patent and Trademark Office and courts have found methods of medical treatment patentable since 1954.<sup>190</sup> In 1948, together with the courts, the AMA acknowledged that investment and research into medical processes needed adequate protection, and did not consider medical methods patents unethical.<sup>191</sup>

However, further to a single patent lawsuit, *Pallin v Singer*,<sup>192</sup> which provoked extensive debate over medical procedure patents and lobbying of the US Congress by the AMA coalition, the American patent code was radically changed by excluding medical practitioners and related health care entities from liability for infringement of medical procedure patents.<sup>193</sup>

### 3.6 CONCLUSIONS – COMPARATIVE ANALYSIS

The above review of patenting of methods of medical treatment in countries outside Australia reveals that there is no clear-cut pattern. Each country deals with this matter in its own way, either by expressly prohibiting methods of treatment from patenting,<sup>194</sup> or by providing no prohibition in the statute and leaving the matter for the courts to deal with,<sup>195</sup> or even by allowing such methods to be patentable, by placing a broad definition of 'invention' in the legislation, but protecting some users from infringement actions.<sup>196</sup>

In cases where patent legislation does not expressly prohibit surgical or therapeutic methods from patenting, it appears that the courts have been reluctant to allow patents for such methods. The Canadian and New Zealand courts, for instance, consider methods of medical treatment as inherently unpatentable.<sup>197</sup> Furthermore, the New Zealand courts treat patents to such methods as generally

---

<sup>190</sup> See *Ex Parte Scherer*, 103 USPQ (BNA) 107.

<sup>191</sup> See William Noonan, 'Patenting Medical Surgical Procedures' (1995) 77 *Journal of the Patent and Trademark Office Society* 651, 654.

<sup>192</sup> 36 USPQ 2d (BNA) 1050 (D Vt 1995).

<sup>193</sup> HR 3610, 104<sup>th</sup> Congress (1996), which become Public Law No 104-208 (Public Law No 104-208).

<sup>194</sup> See Section 7 of the *Patents Act 1967* (Israel).

<sup>195</sup> See Section 2 of the *Patents Act*, R.S.C. 1985, P-4 (Canada) and Section 2 of the *Patents Act 1953* (New Zealand).

<sup>196</sup> See 35 US Code § 101 (1994).

<sup>197</sup> *Tennessee Eastman Co v The Commissioner* (1972), 8 CPR (2d) 202; (1972) 33 DLR (3d) 459; *Pfizer Inc v Commissioner of Patents* [2004] NZCA 104.

inconvenient within s 6 of the Statute of Monopolies.<sup>198</sup> The courts in the US also originally were opposed to patentability of methods of medical treatment. However, the long practice of prohibition was rejected in *Scherer*<sup>199</sup> where the Board of Patent Appeals ruled that medical processes were patentable subject matter in the US.<sup>200</sup>

After observation of legislation and case law of each jurisdiction, it is now possible to highlight the important features of the relevant law in each of those jurisdictions, as follows.

### 3.6.1 Key Features of Canadian Law

Although methods of medical treatment are not directly patentable in Canada, using a format '*for the use of* a drug or device' and leaving the step of performing a medical procedure or administering a drug outside of the scope of the claim, such methods can be patented indirectly.

It is important to emphasise that while the format '*for the use of...*' would be allowed in Canada, it would likely be disallowed in Europe, Israel and New Zealand since it is viewed as being a therapeutic treatment of the human or animal body.<sup>201</sup> A European, Israeli or New Zealand patent can only be granted to a claim directed to *the use of a compound* for the *manufacture* of a medicament intended for a specified new and inventive therapeutic treatment. While some might argue that both formats are similar, as they are directed to the purpose, it seems that the format '*for the use of...*' is not considered as being a Swiss-type claim in Canada.

It is submitted that by allowing this format in Canada the Patent Appeal Board of the Canadian Patent Office has taken a more flexible approach to the existing position with patentability of medical treatments. The Canadian format '*for the use of...*', is not required to be for the *manufacture* of a medicament. It is directed to *the use*, and is the same as the claim *directed to treat a disease* in human beings, thus can be considered as a 'method of medical treatment'.

---

<sup>198</sup> *Pfizer Inc v Commissioner of Patents* [2004] NZCA 104.

<sup>199</sup> 103 U.S.P.Q. 107 (Pat. Off. Bd. App. 1954).

<sup>200</sup> *Ex Parte Scherer* 103 U.S.P.Q. 107 (Pat. Off. Bd. App. 1954), 110.

<sup>201</sup> See *Eisai/Second Medical Indication* (1985) OJ EPO 60; *John Wyeth & Brother Ltd's Application*; and *Schering A.G's Application* [1985] RPC 545; Israel Patent Office Claims Practice in Materials, Chemical and Pharmaceutical Cases- Part II, Directive No.40; *Pharmaceutical Management Agency Ltd v Commissioner of Patents* [1999] NZCA 332.



The Canadian cases<sup>202</sup> also suggest that the Board is willing to take a narrow view of the phrase 'medical treatment' and allow the claims where it is possible to obtain a claimed result without the use of professional medical knowledge and skill. It seems clear that diagnostic methods, apparatus and substances are patentable in Canada. However, there are still some genuine issues of characterization as to whether or not a new medical use of a known substance is, in effect, a method of medical treatment, and therefore unpatentable.

### 3.6.2 Key Features of Israeli Law

The scope of the Israeli Act is clear: it expressly excludes methods of therapeutic treatment of the human body by virtue of s 7. This situation is similar to that of the UK and the EPC. On the other hand, Israeli position is in contradiction to the provision in Art 52(4) EPC, which prohibits all methods of surgery, therapy and diagnosis. These methods are in fact allowable in Israel when applied to non-human animals. This situation is similar to that of New Zealand. Furthermore, Israel is in line with European and New Zealand approach in allowing the first and second therapeutic use claims in the form '*use of X in the manufacture of the medicament Y*'.

Though methods of medical treatment are currently not patentable in Israel, the case law of this country includes the valuable decision of the *Wellcome Foundation*<sup>203</sup> case. Although this case has had little influence on current Israeli law to date, arguably, it made significant contributions towards changing attitudes about patentability of such methods in Australia, as will be seen in the next Chapter, and it may still play a valuable role in Israeli patent law in the future.

### 3.6.3 Key Features of New Zealand Law

After the decision in *Pharmaceutical Management Agency* the New Zealand Patent Office has adopted two distinct approaches: while it recognized new methods of treatment of humans as *inventions* and allowed all claims for the methods of treatment of humans, at the same time it did not allow claims where the identified treatment related to the surgery on humans or to the treatment of illness or disease. The exclusion from patentability of methods of medical treatment is based on policy grounds,<sup>204</sup> mainly, that the use of such methods would be contrary to

---

<sup>202</sup> *Merck & Co v Apotex* (1995) 59 CPR (3d) 133; *Re Application No. 016, 962*; *Re Application No. 880, 719* and *Re Application No. 372,233*.

<sup>203</sup> *Wellcome Foundation Ltd v Plantex Ltd* [1974] RPC 514.

<sup>204</sup> *Pharmaceutical Management Agency Ltd v Commissioner of Patents* [1999] NZCA 332, [29].

morality.<sup>205</sup> From this it could be followed that the definition of 'methods of medical treatment' is broader, in some circumstances, than that adopted by the European Patent Office or the UK Patent Office.

Further, the decision in *Pfizer*, where the Court of Appeal ruled that methods of medical treatment do not meet the definition of 'invention', such methods cannot be patented in New Zealand. This position is in line with Canadian position. Though Pfizer Inc suggested permitting claims under consideration on the condition that the patentee makes a disclaimer of any right to sue the medical practitioner (similar to that of required under the addition to 35 US Code, § 287(c)) the court in *Pfizer* rejected that suggestion and left this issue for Parliament to decide. However, according to the draft Patents Bill 2004 released by the New Zealand Government, this suggestion will not be followed. It seems that the draft Bill seeks to bring the New Zealand patent legislation into line with global norms. As stated above, the draft Bill contains specific exclusions to patentability of diagnostic, therapeutic or surgical methods for the treatment of human beings. This exclusion for methods of medical treatment is in line with the exclusion adopted in Israel, Europe under Art 52(4) EPC and the UK.

With regards to second therapeutic use claims, New Zealand patent law is now in line with European and Israeli patent law and allows Swiss-type claims in the form '*use of X in the manufacture of the medicament Y*'. It clearly goes some way towards satisfying the concerns of the pharmaceutical industry.

It should also be noted that New Zealand's patent law stands in marked contrast to the Australian regime, which is discussed in the next Chapter.

#### **3.6.4 Implications of Canadian, Israeli and New Zealand Laws on the Medical Profession in Each Country.**

##### **Hypothetical example: procedure for the preparation of a donor bone marrow transplant**

Notwithstanding that there is no clear-cut pattern in approach of prohibiting methods of medical treatment in Canada, Israel and New Zealand, overall, these countries have a number of similarities in terms of outcome. In particular, although 'pure' methods are not patentable, some such methods are indirectly patentable through the vehicle of the first and second therapeutic use, or Swiss-type claims involving a use of medicament. The only slight difference in dealing with Swiss-

---

<sup>205</sup> By virtue of s 17 of the *Patents Act 1953*.

type claiming in these countries relates to the format '*for the use of...*'. As discussed above, this format would be allowed in Canada, and disallowed in UK, Europe, Israel and New Zealand.

As a consequence of these findings, the impact of Canada, Israel and New Zealand laws relating to the patentability of methods of medical treatment on the medical profession in each country can be illustrated by using a single hypothetical example.

Consider a hypothetical physician who has invented and patented a cure for a current unsolved problem with so-called graft-versus-host disease, which makes a bone marrow transplant procedure hopeless for many leukemia patients. This disease is an immune reaction of the donor bone marrow against the recipient tissues. In other words, the donor bone marrow does not take properly in the recipient's body, and attacks the recipient's tissues instead.

Our hypothetical physician has invented a method for the preparation of donor bone marrow. This preparation can decrease the immune reaction against the recipient's tissues and make a donor bone marrow 'take' well. Under Canadian, Israeli and New Zealand laws, that physician may or may not be able to patent this invention. The result depends upon the format used for the patent application.

- '*The method for...*' format

Assume the hypothetical physician wishes to obtain a patent on a pure '*method for the preparation of a donor bone marrow*'. Under these laws, he will not be able to patent this invention as this claim will clearly fall into the narrow view of the term of '*medical treatment*', since its performance requires the use of professional medical knowledge and skill.

- '*The use of a device*' format

Assume the hypothetical physician invents a new *device* that can be used for preparation of bone marrow. Making a general patent claim for '*the use of a device*' and omitting the step of performing a *medical procedure*, he would be able to obtain a patent protection for this invention.

- '*The new use of a known drug X*' format

Suppose the hypothetical physician discovers that an *already known drug X* for a certain method, can be used in a *new way* to suppress the immune system to allow donor bone marrow to 'take' well. Under Canadian, Israeli and New Zealand laws, the physician can patent *the new use of the drug X*, provided that the claim is not seeking a patent protection for administering this drug.

- 'The procedure, using the drug X' format

Suppose that the hypothetical physician discovers that the drug X, when used as described in the patent specification, *in combination with a surgical procedure* invented by the hypothetical physician, substantially decreases the graft-versus-host disease. If the physician chooses to obtain a patent on the *procedure, using the drug X*, the patent would not be allowed, since it would clearly be a 'pure' method of medical treatment claim.

The above examples illustrate that some methods are indeed indirectly patentable. The basis for this argument is that in a case of a second therapeutic use claim, the underlying compound is not new and therefore cannot be the subject of the patent claim, all that remains to be patented is the *new use* of that compound, which primarily directs to the medical treatment.

### 3.6.5 The United States

#### 3.6.5.1 Key Features of US Law

The main feature of US law is that new Public Law 104-208 gives medical practitioners and related health care entities a statutory exemption from liability for infringement of medical procedure patents.

On one hand it could be argued that the Public Law 104-208 is rigid in that even though it does not exclude methods of medical treatment from patentability, it makes such patents unenforceable against medical practitioners and related health care entities, unless they fall under one of three exceptions (§ 616(c)(2)(A)(i-iii)).<sup>206</sup> Further, it could be said that the new law deprives the patent owner of the right to sue for damages or seek injunctive relief when licensed medical practitioners engaging in medical activities infringe their patents. Accordingly, it could be concluded that, due to Public Law 104-208, the law in the US is not different from

---

<sup>206</sup> Many American authors argue that § 287 (c) is practically equivalent to a ban on medical methods patents, as it renders such patents meaningless. See, eg, Gocyk –Farber, above n 120; Nichols, above n 109; Anderson, above n 147.

that in Canada, Israel, New Zealand or UK. Thus, from practical point of view, the US position is in line with the international position of exclusion of methods of medical treatment from patentability.

On the other hand one must admit that by allowing a physician to enforce a patent for a medical or surgical procedure when the infringer's activity also infringes an unexpired patent for a medical machine/device, composition/drug or method of their use, the Public Law 104-208 still provide some scope for physicians to enforce patents involving methods of medical treatment. In this way, in contrast to the UK and other reviewed countries, US law regarding such patents is much more liberal.

Furthermore, notwithstanding the new amendments, the practice of the US, in allowing patenting of methods of medical treatment, still could provide useful directions or alternatives for solving the debate concerning patentability of such methods in Australia and around the globe. This conclusion will be discussed in detail in Chapter 6.

In relation to indirect patenting of methods of medical treatment via vehicles of Swiss-type claim, compare to the Canadian, Israeli and New Zealand's approaches, US' approach clearly eliminates any need for such claims. This is because Public Law 104-208 provides protection for 'uses of compositions'.<sup>207</sup> In this way methods of medical treatments can also be indirectly enforced in the US.

The following hypothetical example illustrates the difference between the US approach and approaches adopted by other reviewed countries in dealing with patenting of medical inventions. It will be evident from this example that similar cases will be treated differently under US' and other approaches.

#### **3.6.5.2 Implications of US patent law on the US medical profession**

##### **Hypothetical example: procedure for the preparation of a donor bone marrow transplant**

Adopting the hypothetical discussed above, let us consider another hypothetical physician, this time in the US, who has invented and patented a cure for a current unsolved problem with so-called graft-versus-host disease. Under US law, that physician may or may not be able to enforce his patent. The result depends on whether one of three exceptions in § 616(c)(2)(A)(i-iii) applies.

---

<sup>207</sup> See § 616 (c)(2)(A) of Title 35 US Code § 287 (c).

- § 616(c)(2)(A)(i) *the use of a patented machine, manufacture, or composition of matter in violation of such a patent*

Assume the hypothetical physician has invented a new *machine* that can be used for preparation of bone marrow and has obtained a patent for 'the machine and its use'. Under this provision, the physician may enforce the patent on the machine and on the *procedure for using this machine*.

Suppose our hypothetical physician has discovered that an *already patented composition* can be used in a *new way* to suppress the immune system to allow donor bone marrow to 'take' well. If the physician is able to satisfy the patenting requirements and obtain a patent on the *new method of using the composition*, the patent would be enforceable under this provision.

- § 616(c)(2)(A)(ii) *the practice of a patented use of a composition of matter in violation of such patent*

Suppose someone else had already patented *drug X*, to suppress the immune system to allow donor bone marrow to 'take'. Suppose that the hypothetical physician discovers that drug X, when used as described in the patent specification, *in combination with a surgical procedure* invented by her, substantially decreases the graft-versus-host disease. If the physician is able to satisfy the patenting requirements and obtain a patent on the *procedure using the drug X*, the patent would be enforceable under this provision.

- § 616(c)(2)(A)(iii) *the practice of a process in violation of a biotechnology patent*

Assume someone else had already patented a *biotechnological invention* to generate new cells that would suppress the immune system to allow donor bone marrow to 'take' well. Suppose, *in combination with a surgical procedure* invented by the hypothetical physician, these new cells would substantially decrease the graft-versus-host disease. If the physician is able to satisfy the patenting requirements and obtain a patent on the *procedure, using the patented cells*, the patent would be enforceable under this provision.

- *Enforcement of an unexpired patent for a machine/device, composition/drug or method of their use that fall under one of three exceptions above (§ 616(c)(2)(A)(i-iii))*

Assume the hypothetical physician is the owner of a patent for a *machine* that can be used for preparation of bone marrow or the *procedure using the drug X* discussed above. Assume someone infringes this patent. Public Law 104-208 allows the hypothetical physician to enforce such patents provided that they are unexpired patents. However, the hypothetical physician will not be able to enforce

his right under a patent for a medical or surgical procedure using a *machine, drug or method of their use* when such machine, drug or method of their use are not patented or their patents are already expired.

- *Enforcement of a patent for medical and/or surgical procedure that falls outside one of three exceptions above (§ 616(c)(2)(A)(i-iii))*

Assume the hypothetical physician is the owner of a patent for medical and/or surgical procedure that falls outside one of three exceptions under § 616(c)(2)(A)(i-iii), and someone infringes this patent. The hypothetical physician will not be able to enforce his right under this patent against medical practitioners and related health care entities.

## CHAPTER 4: PATENTING OF METHODS OF MEDICAL TREATMENT IN AUSTRALIA

'No one has advanced a just and logical reason why reward for service to the public should be extended to the inventor of a mechanical toy and denied to the genius whose patience, foresight, and effort have given a valuable new [discovery] to mankind'<sup>1</sup>

H.R. Rep. No. 71-1129, at 2 (1930)

### 4.1 INTRODUCTION

The review of the law in relating to the patentability of methods of medical treatment the UK, Europe and other common law countries presented in Chapters 1 – 3 of this thesis provides the backdrop against which relevant Australian law can now be critically analysed.

Similar to the United Kingdom patent law prior to the *Patents Act 1977* (UK), Australian patent law originates from the *Statute of Monopolies 1624* (the ***Statute of Monopolies***), which remains the touchstone of patentability in the *Patents Act 1990* (Cth) (the ***1990 Act***). The Australian legislation, like its New Zealand and Canadian counterparts, does not expressly prohibit patenting of methods of medical treatment, and so the issue has been left to the courts to determine. Thus, the 1990 Act continues a longstanding legislative tradition of relying on the broad and flexible power of the courts to decide what is suitable subject matter for the grant of letters patent, and in doing so, provides little or no guidance on whether methods of medical treatment could be such a subject matter.

Until 1992<sup>2</sup> Australian courts did not directly deal with the issue of whether a new method of treating the human body could be protected under patent law. There was no Australian judicial decision that, as part of its *ratio decidendi*, firmly pronounced on the exclusion from patentability of methods of medical treatment and its basis. However, some *obiter* observations were made on the issue.<sup>3</sup>

<sup>1</sup> H.R. Rep. No. 71-1129, 2 (1930).

<sup>2</sup> In *Anaesthetic Supplies Pty Ltd v Rescare Ltd* (1992) 111 ALR 205.

<sup>3</sup> See, eg, *Maeder v Busch* (1938) 59 CLR 684, 699; *National Research Development Corporation v Commissioner of Patents* (1959) 102 CLR 252, 270, 275; *Joos v Commissioner of Patents* (1972) 126 CLR 611, 619.



## 4.2 RELEVANT STATUTORY PROVISIONS

The *Patents Act 1903* (Cth) (the **1903 Act**), the first patent legislation passed by the Commonwealth Parliament, was based on the United Kingdom *Patents, Designs, and Trade Marks Act*, 1883 to 1888 (amended by the *Patents Acts* of 1901 and 1902 and repealed by the *Patents and Designs Act 1907*). The 1903 Act defined 'invention' in s 4 in the same terms used by the 1907 Act (UK) by reference to the established ambit of s 6 of the *Statute of Monopolies*, and contained no specific exclusion for methods of human treatment.

Following the Swan Committee Report in 1947, the United Kingdom legislation was replaced by the *Patents Act 1949* (UK). Following these developments in the United Kingdom, the Australian Attorney-General established a Committee in 1950 to review Australian patent law. The Committee reported in 1952 and recommended a Bill, which was passed as the *Patents Act 1952* (the **1952 Act**) without substantial alteration. The 1952 Act was similar to the *Patents Act 1949* (UK). The definition of 'invention' in s 6 of the 1952 Act remained unchanged and, like its 1903 predecessor, defined the word 'invention' by reference to the s 6 of the *Statute of Monopolies*. Again, the 1952 Act contained no specific provision for methods of human treatment.

As discussed earlier in Chapter 2, the *Patents Act 1977* (UK) completely replaced the old system of English patent law. One of the radical changes, in particular, was the express prohibition of methods of medical treatment from patenting, declaring them as not capable of industrial application.<sup>4</sup>

In Australia, as a result of a reference in October 1979 from the Minister of Productivity, the Industrial Property Advisory Committee (**IPAC**) undertook a major review of the patent system. The terms of reference were very wide: to review all the economic, legal and administrative complexities of the patent system.<sup>5</sup> In August 1984 IPAC submitted its report to the Minister of Science.<sup>6</sup> On IPAC's recommendation a working party was established to assist in the drafting of a Bill. As a consequence, the Patents Bill 1989 was introduced, which provided for replacement of the 1952 Act. The Bill passed both houses in October 1990 and resulted in enactment of the 1990 Act, which came into operation on 1 May 1991.

---

<sup>4</sup> *Patents Act 1977*, s 4(2).

<sup>5</sup> Donald Speagle and Michael Dowling, 'The 1990 Patents Act: Unfinished Reform' (1993) *Australian Intellectual Property Journal*, 166.

<sup>6</sup> *Patents, Innovations and Competition in Australia* (the IPAC Report).

Like its predecessor, the 1990 Act is silent about patenting of methods of medical treatment. The Australian Parliament chose not to follow the United Kingdom approach of excluding methods of medical treatment from the scope of patentable subject matter. Instead it decided 'not to build this particular exclusion into its legislation',<sup>7</sup> despite having excluded other categories of subject matter, such as 'human beings, and the biological processes for their generation'.<sup>8</sup>

### 4.3 THE REQUIREMENTS FOR A VALID PATENT

#### 4.3.1 Requirements of s18(1)

Before discussing the patentability of methods of medical treatments, it is necessary to make some observations about requirements for a valid patent under s18(1) of the 1990 Act, which defines a 'patentable invention' as one that:

- (a) is a manner of manufacture within the meaning of s 6 of the Statute of Monopolies; and
- (b) when compared to the prior art base as it existed before the priority date of the claim:
  - (i) is novel; and
  - (ii) involves an inventive step; and
- (c) is useful; and
- (d) was not secretly used in the patent area...

Schedule 1 of the 1990 Act provides that a 'patentable invention' means 'an invention of the kind mentioned in S 18'. Schedule 1 provides further that an 'invention' means:

any manner of new manufacture the subject of letters patent and grant of privilege within S 6 of the *Statute of Monopolies*, and includes an alleged invention.

It is important to recall that s 6 of the *Statute of Monopolies* declared all monopolies void, but saved those that are manners of manufacture that are not 'contrary to the law or mischievous to the State by raising prices of commodities at home, or hurt of trade, or generally inconvenient.'

---

<sup>7</sup> *Anaesthetic Supplies Pty Ltd v Rescare Ltd* (1994) 122 ALR 141, 182 (Wilcox J).

<sup>8</sup> See *Patents Act* 1990 (Cth), s 18 (2).

Due to the overlapping concepts of 'patentable invention', 'invention', 'newness', 'novelty' and 'manner of new manufacture', identifying the boundaries of each requirement is no easy task. This Chapter deals with them in some length to show that all Australian patent applications have to go through the complicated channels to satisfy the requirements set out in s18(1), including methods of medical treatment.

#### 4.3.2 Novelty and Inventive Step Requirements

Since the central change made by the 1990 Act was an adjustment of the novelty and inventive step requirements, it is necessary to deal with these requirements first.<sup>9</sup> Under the 1952 Act the above requirements of invention had to be inferred from the provisions in Ss 59(1) and 100(1), dealing with opposition and revocation proceedings. Neither the 1903 Act nor the 1952 Act contained an express provision giving an examiner power to examine an application for lack of an inventive step.<sup>10</sup> This absence of the inventive step requirement had considerable implications on the interpretation by the courts of the scope of what was embraced by s 6 of the *Statute of Monopolies*. Thus, the High Court decisions, operating under 1903 and 1952 Acts,<sup>11</sup> show that the rationale for refusing analogous use claims<sup>12</sup> is conceptually consistent with earlier English cases,<sup>13</sup> namely, a failure to meet a *threshold requirement of inventiveness*, independent of the requirement of an *inventive step*.

The 1990 Act expressly codified the inventive step and novelty requirements of patentability. Section 7 lays down the bases of comparison for determining the s18(1)(b) requirements that the invention be novel and involve an inventive step. These bases require a comparison of the invention against information external to the patent specification at issue. For novelty, the basis of comparison is found in s 7(1). For an inventive step, the basis of comparison is found in Ss 7(2) and (3). Schedule 1 provides the definitions of 'prior art information' and 'prior art base'.

---

<sup>9</sup> It should be noted that the novelty and inventive step requirements have since been further amended by the *Patents Amendment Act 2001* (Cth).

<sup>10</sup> See, for example s 48(1) of the 1952 Act.

<sup>11</sup> *Commissioner of Patents v Microcell* (1959) 102 CLR 232; *National Research Development Corporation v Commissioner of Patents* (1959) 102 CLR 252.

<sup>12</sup> An 'analogous use' claims will be the claims where, on the face of the specification, a claim was 'nothing but a claim for the use of a known material in the manufacture of a known articles for a purpose of which its known properties make that material suitable': See *Commissioner of Patents v Microcell* (1959) 102 CLR 232, 251 (Dixon CJ; McTiernan, Fullagar, Taylor and Windeyer JJ).

<sup>13</sup> *Re Compagnies Reunies des Glaces et Verres Speciaux du Nord de la France* (1930) 48 RPC 185; *Re L & G's Patent* (1940) 58 RPC 21.

The explicit inclusion of the inventive step in the 1990 Act means that in the case when an alleged invention lacks inventiveness, it will be refused at the examination stage. Theoretically, the inclusion of separate requirements of novelty and inventive step should have solved the confusion about the test of inventiveness. However, the High Court's decision in *NV Philips Gloeilampenfabrieken v Mirabella International Pty Ltd*<sup>14</sup> (*Philips*) added a further layer of complexity by imposing an additional threshold requirement that the claimed subject-matter exhibits 'the quality of inventiveness' on the face of the specification. While the definition of a valid patent in s 18 of the 1990 Act appears simple in theory, in practice the separation of each requirement is a difficult task.<sup>15</sup> For example, to define 'obviousness' it is necessary to refer to Ss 7 and 18 and several definitions in Schedule 1 of the 1990 Act.

#### 4.3.3 'Patentable Invention' Within the Meaning of the Opening Words of Ss18(1) and 18(1)(a)

The first step in the complicated exercise of determining the patentability of an invention involves a determination of the meaning of the following:

1. 'patentable invention' within the opening words of s18(1), which states that: 'a patentable invention is an invention that...' (the **opening words**); and an 'invention' in Schedule 1, which states that: 'any manner of *new* manufacture'<sup>16</sup> the subject of letters patent...' (the **threshold test of an 'invention'**); and
2. a 'manner of manufacture' within the meaning of s 6 of the Statute of Monopolies<sup>17</sup> in s18(1)(a) (a **'manner of manufacture'**).

##### 4.3.3.1 The opening words of s18(1): 'a patentable invention is an invention that...'

According to the important patent decision of the High Court of Australia in *Philips*<sup>18</sup> the fulfillment of the primary or threshold test of an 'invention' is the prerequisite to the assessment of *any* invention. Although this issue is outside of the scope of this thesis and not intended to be discussed in depth, since the non-fulfillment of the

<sup>14</sup> (1995) 132 ALR 117, 121 (Brennan, Deane and Toohey JJ).

<sup>15</sup> See also *Aktiebolaget Hassle v Alphapharm Pty Ltd* [2002] HCA 59 and *Lockwood Security Products v Doric Products* (2004) HCA 58 regarding application of requirement of inventive step.

<sup>16</sup> Note the inclusion of 'new'. Compare to s 18(1)(a).

<sup>17</sup> Note the omission of 'new' in paragraph (a). Compare to the definition of 'invention' in Schedule 1.

<sup>18</sup> (1995) 183 CLR 655.

threshold test would continue to exclude from patentability any claimed invention, including methods of medical treatment, it will be necessary to briefly discuss the meaning of this test.

The threshold test of invention was applied for the first time in *Commissioner of Patents v Microcell*<sup>19</sup> (**Microcell**) (decided under the 1903 Act) and derived from the issue of whether there was a manner of manufacture and the requirement that claimed subject-matter exhibited 'the quality of inventiveness'. This test requires an assessment whether claimed invention is 'new' or 'inventive'. As it follows from the more recent decision *Philips*, this requirement is *independent* of the specific provisions of novelty and inventive step (located in s18(1)(b) of the 1990 Act), and is the primary requirement that must be addressed by the examiner. The essence of the decision in *Philips* can be seen in the following statement:

The effect of those opening words of Section 18(1) is that the primary or threshold requirement of a 'patentable invention' is that it be an 'invention'. Read in the context of Section 18(1) as a whole and the definition of 'invention' in the Dictionary in Schedule 1, that clearly means 'an alleged invention', that is to say, an 'alleged' 'manner of new manufacture the subject of letters patent and grant of privilege within Section 6 of the *Statute of Monopolies*'.<sup>20</sup>

A majority of the Court (per Brennan, Deane and Toohey JJ) confirmed the existence of the threshold test of patentability when considering the issue of whether there is a manner of manufacture, applied in *Microcell*. However, the High Court focused not upon the words of s18(1)(a) 'is a manner of manufacture...', as the Full Federal Court had done, but upon the opening words of s18(1) 'a patentable invention is an invention that ...'. The court's interpretation of the opening words were that:

...if it is apparent on the face of the specification that the quality of inventiveness necessary for there to be a proper subject of letters patent under the *Statute of Monopolies* is absent, one need go no further.<sup>21</sup>

In other words, the threshold test is an assessment of 'newness' or 'inventiveness' on the face of the specification. This assessment must be done without need to resort to s18(1)(b), a codified provision for novelty and inventive step. If the

---

<sup>19</sup> (1959) 102 CLR 232.

<sup>20</sup> (1995) 183 CLR 655, 663 (Brennan, Deane and Toohey JJ).

<sup>21</sup> *NV Philips Gloeilampenfabrieken v Mirabella International Pty Ltd* (1995) 132 ALR 117,122.

examiner finds that there is no 'invention' within the meaning of the opening words of s18(1), 'one need go no further'.<sup>22</sup>

This approach is consistent with that taken previously by the High Court in *Microcell*. However, it must be remembered that *Microcell* was considered in the context of the provisions of the 1903 Act, under which the requirements of novelty and inventive step had to be inferred from other sources.<sup>23</sup> This Act did not contain an express requirement of inventive step.<sup>24</sup> Therefore, the court in *Microcell* interpreted the scope of what is meant by s 6 of the *Statute of Monopolies* in the light of the *threshold requirement of inventiveness*, independent of the requirement of inventive step.<sup>25</sup>

The *Philips* case, however, was decided under the 1990 Act, which expressly codified the inventive step requirement of patentability by virtue of s18(1)(b)(ii). Therefore, one might expect that the more directed provisions of the 1990 Act required a different approach to statutory interpretation of 'patentable invention'. Yet, the High Court in *Philips* confirmed the existence of a threshold test, and so created uncertainty as to how the limits of this test are to be established.<sup>26</sup> *Philips'* interpretation of the opening words of s18(1) as the requirement for a threshold test raises the question of what operation remains for s18(1)(b)(ii) and requirement of inventive step in s 7 (2) and (3), which expressly provide for the inquiry to the inventiveness. It gave no guidance as to the criteria the court would apply in assessing the requirements for novelty and inventive step.

The requirement for a threshold test clearly creates overlapping grounds of invalidity, such as 'manner of manufacture', 'novelty' and 'inventive step' under the 1990 Act. It has been proposed therefore that under the 1990 Act an examination of inventive step beyond the face of the specification ought only to be undertaken within Ss18(1)(b)(ii), 7(2) and (3).<sup>27</sup>

---

<sup>22</sup> Ibid.

<sup>23</sup> For example, Ss 59(1) and 100(1) of the 1952 Act, dealing with opposition and revocation proceedings.

<sup>24</sup> See, for example s 48(1), of the *Patents Act 1952* (Cth).

<sup>25</sup> In *Lockwood Security Products v Doric Products* (2004) HCA 58 the High Court cleared the decision in *Microcell* relating to inventive step. This case confirmed that it is irrelevant whether the invention was arrived at as a matter of chance or the result of great intellectual effort. Further this decision it will be harder to invalidate a patent on the basis of obviousness.

<sup>26</sup> Miranda Duigan and Michael Dowling, 'Threshold Test of Manner of Manufacture in Australia-What Next?' (1998) *Patent World*, September, 26.

<sup>27</sup> David Brennan and Andrew Christie, 'Patent Claims for Analogous Use and the Threshold Requirement of Inventiveness' (1997) 25 *Federal Law Review* 237, 259.

The decision in *Philips* created confusion and thus was interpreted in various ways by academics,<sup>28</sup> legal practitioners<sup>29</sup> and courts.<sup>30</sup> The most recent interpretation of this decision was made by the Full Court of the Federal Court in *Bristol-Myers Squibb Co v F H Faulding & Co Ltd (BMS)*, when the court said:

In our view, in the light of the authorities to which we have referred, *Philips* stands for the proposition (as a matter of construction of the 1990 Act) that if, on the basis of what was known, as revealed on the face of the specification, the invention claimed was obvious or did not involve an inventive step- that is, would be obvious to the hypothetical non-inventive and unimaginative skilled worker in the field (*Minnesota* at 260 per Barwick CJ) - then the threshold requirement of inventiveness is not met.<sup>31</sup>

#### 4.3.3.2 Section 18(1)(a): 'a manner of manufacture...'

In considering the meaning of s18(1)(a), the High Court in *Philips* made the *obiter* remark that the phrase 'manner of manufacture within the meaning of s 6 of the Statute of Monopolies' should be understood as referring to a process which is a proper subject matter of letters patent according to the traditional principle.<sup>32</sup> In other words, s18(1)(a) should be construed to deal exclusively with the 'pure' manner of manufacture question dealt with by the High Court in *National Research Development Corporation v Commissioner of Patents (NRDC)*<sup>33</sup> This matter is not considered under the opening words of s18(1). Therefore, s18(1) and s18(1)(a) involve two separate 'manner of manufacture' inquiries, namely:

1. the threshold test of invention, in the sense applied in *Microcell*<sup>34</sup> and addressed by *Philips*<sup>35</sup>; and

<sup>28</sup> Brennan and Christie, above n 27; William van Caenegem, 'Technicality Requirement, Patent Scope and Patentable Subject Matter in Australia' (2002) 13 *Australian Intellectual Property Journal* 41; William van Caenegem, *Intellectual Property Law and Innovation* (2007).

<sup>29</sup> Duigan and Dowling, above n 26; Mary Padbury, 'Inventiveness apart from Novelty and Inventive Step- The High Court's Decisions on Manner of Manufacture in *Philips* and *Ramset*' (1998) *Australian Intellectual Property Journal*, 161.

<sup>30</sup> *Advanced Building System Pty & Anor v Ramset Fasteners (Aust) Pty Ltd* (1998) 152 ALR 604.

<sup>31</sup> *Bristol-Myers Squibb Co v F H Faulding & Co Ltd* [2000] FCA 316, [30].

<sup>32</sup> *NV Philips Gloeilampenfabrieken v Mirabella International Pty Ltd* (1995) 183 CLR 117, 167.

<sup>33</sup> Brennan and Christie, above n 27, 258.

<sup>34</sup> *Commissioner of Patents v Microcell* (1959) 102 CLR 232.

<sup>35</sup> *NV Philips Gloeilampenfabrieken v Mirabella International Pty Ltd* (1995) 132 ALR 117; *Advanced Building System Pty & Anor v Ramset Fasteners (Aust) Pty Ltd* (1998) 152 ALR 604.

2. a 'pure' manner of manufacture test, in the sense of the central question discussed in *NRDC*<sup>36</sup> (**pure manner of manufacture test**).

This second pure manner of manufacture test requires more detailed treatment because this test has played a critical role in determining the patentability of medical treatment inventions. In 1984, after reviewing the 1952 Act, IPAC strongly recommended that there should not be inflexible codified definition of 'manner of manufacture' (as did the *European Patent Convention* and the *Patents Act 1977* (UK)), and that the manner of manufacture test should be retained in its existing form.<sup>37</sup> The IPAC stated that the concept of 'manner of manufacture' had 'the advantage of being underpinned by an extensive body of decided case law which facilitates its application in particular circumstances'.<sup>38</sup> IPAC emphasized that the real importance of the test lies in its capacity to respond flexibly to new technological developments. Consequently, Parliament chose to leave the definition of invention uncoded, instead retaining the manner of manufacture test in s18(1)(a) of the 1990 Act.

#### 4.4 THE PURE MANNER OF MANUFACTURE TEST

##### 4.4.1 Historical Development of the *Manner of Manufacture* Concept

The concept of manner of manufacture has a long history, and its development can be traced back to the early English case law. Numerous attempts were made to interpret the meaning of s 6 of the *Statute of Monopolies* by exact verbal formula, and to make a precise codified definition. For example, in *Boulton v Bull*,<sup>39</sup> which involved a patent for a new method of using an old steam engine in a more economical way, three of the Judges<sup>40</sup> treated the said 'manufacture' within the meaning of s 6 of the *Statute of Monopolies*.<sup>41</sup> Eyre CJ explained that the word 'manufacture' extended 'to any new results of principles carried into practice...new processes in any art producing effects useful to the public'.<sup>42</sup>

In his dissenting judgment, Rooke J, although relying on the *Statute of Monopolies*, was more inclined to support the patent on the basis of the 'spirit' of s 6 and its

---

<sup>36</sup> *National Research Development Corporation v Commissioner of Patents* (1959) 102 CLR 252.

<sup>37</sup> See the IPAC Report, above n 6, 41.

<sup>38</sup> See, the IPAC Report, above n 6, 41.

<sup>39</sup> (1795) 126 ER 651.

<sup>40</sup> Per Eyre CJ, Buller and Heath JJ.

<sup>41</sup> *Boulton v Bull* (1795) 126 ER 651, 660-1 (Heath J), 663 (Buller J) and 665-7 (Eyre CJ).

<sup>42</sup> *Boulton v Bull* (1795) 126 ER 651.



concept of manufacture.<sup>43</sup> According to his Honour, the spirit of s 6 supported the patent, for there had been a new and useful improvement in fire engines sufficiently described in the specification.<sup>44</sup> This view was accepted over 150 years later by the High Court in *NRDC*.

In *Crane v Price*<sup>45</sup> it was clarified that the term 'manufacture' was used in the dual sense, which combined both a process and a product. However, at that time it remained unclear whether it was necessary to produce some tangible article, in order to satisfy the requirement of the *Statute of Monopolies*. For example, Abbott CJ proposed in *R v Wheeler*<sup>46</sup> that, to satisfy the word 'manufacture', there must be '[s]omething of a corporeal and substantial nature, something that can be made by man from the matters subjected to his art and skill, or at least some new mode of employing practically his art and skill... '.

These attempts to define the word 'manufacture' led to a 'vendible product' test laid down by Morton J. In the *Matter of an Application for a Patent by GEC*<sup>47</sup> (***GEC's Application***), which significantly narrowed the scope of the inquiry. The 'vendible product' test was discussed in some detail in Chapter 1.<sup>48</sup> The test was difficult to apply in cases where a patent was sought for a new method or process consisting of taking advantage of an unsuspected property of a known material. Thus, there was a need for Morton J's definition to be clarified, and the ambit of 'manner of manufacture' to be expanded by looking at 'manufacture' as a *general concept* founded in the *Statute of Monopolies*.

The time for change was not ripe, however, until 1959, when the High Court of Australia in *NRDC*<sup>49</sup> redefined the test by giving the concept of 'manner of manufacture' an expanded meaning. Although, the question of patentability of methods of medical treatment of the human body was not directly considered by the High Court in *NRDC*, the case became an authority to the issue whether a new method of medical treatment could be a proper subject matter of letters patent.

---

<sup>43</sup> Ibid, 658.

<sup>44</sup> Ibid.

<sup>45</sup> (1842) 1 Webb PC 393; 134 ER 239.

<sup>46</sup> (1819) 106 ER 392, 395.

<sup>47</sup> *In the Matter of an Application for a Patent by GEC* (1942) 60 RPC 1, 4.

<sup>48</sup> See the discussion of *GEC's Application* and the 'vendible product' test in Chapter 1, Part 1.3.2.1 of this thesis.

<sup>49</sup> *National Research Development Corporation v Commissioner of Patents* (1959) 102 CLR 252.

#### **4.4.2 National Research Development Corporation v Commissioner of Patents**

The case concerned a new method for eradicating weeds from crop areas. The active substance of the invention was known, and so not novel. The importance of the invention lay in the discovery of the relationship between particular chemical properties of the known substance and plants, in the way that this known substance selectively killed weeds, without damaging crops. The invention was based on the fact that certain valuable crops did not have a particular enzyme system, which weeds have, so the substance with weedicide properties would only be effective against plants with those particular enzyme systems, not against crops.

The examiner of the application stated that as the active substances of the invention were known, the main Claims 1-3 in the complete specification lodged in support of an application were not directed to any manner of manufacture. Rather, they were claims to the 'mere use of known substances - which use also [did] not result in any vendible product'.<sup>50</sup> Similarly, the Deputy Commissioner of Patents directed that Claims 1- 3 be deleted upon the ground that the method claimed was not a manner of manufacture since it did not result in any vendible product. Since this direction was an equivalent to a refusal of a patent, the National Research Development Corporation appealed to the High Court.

The High Court<sup>51</sup> considered the meaning of the expression 'manner of new manufacture' and the whole concept of a 'manufacture' in the light of two issues: whether the process claimed satisfied the threshold requirement of inventiveness; and whether it had fallen within the category of 'invention' under the 1952 Act.

##### **4.4.2.1 The threshold requirement of inventiveness**

In considering the first issue, the High Court concluded that it was clear that what was claimed was a new process for ridding crop areas of certain kinds of weeds by applying chemicals that *were not known to be useful for this kind of purpose at all*. Therefore, there was a clear assertion of a discovery that a useful result could be attained by doing something to be capable of producing that result.<sup>52</sup> As this was

---

<sup>50</sup> Ibid, 265.

<sup>51</sup> Per Dixon CJ, Kitto and Windeyer JJ.

<sup>52</sup> *National Research Development Corporation v Commissioner of Patents* (1959) 102 CLR 252, 265.

not a claim for a new use of an old substance, it could not be rejected on those grounds.

Even though the substances were known, they were known only partially and, so far as weed-killing potentialities were concerned, were unknown.<sup>53</sup> The Court distinguished the claimed process from previously known processes as it employed substances 'the suggestion of which for the purpose in hand was new, was not obvious, and was to be arrived at only by an exercise of scientific ingenuity, based upon knowledge and applied in experimental research'.<sup>54</sup> The Court concluded that the fact that substances themselves were already known afforded no valid reason for denying inventiveness.

#### **4.4.2.2 Whether the process has fallen within the category of 'invention' under the 1952 Act**

This was the central question of the case. The court looked at the definition of 'invention', which meant 'any manner of new manufacture...', and emphasized that the meaning of 'manufacture' was its main concern. The Court disapproved of any attempt to treat the word 'manufacture' as a rigid statutory formula, and said that the inquiry, which the definition demands, is an inquiry into the scope of the permissible subject matter of letters patent and grants of privilege protected by the s 6 of the *Statute of Monopolies*.<sup>55</sup> The Court noted that it is *an inquiry not into the meaning of a word, but into the breadth of the whole concept or category* under which all grants of patents had been made in accordance with the developed principles of patent law.<sup>56</sup> By emphasizing the breadth of the *Statute of Monopolies* over its literal forms, the Court justified the approach taken by Rooke J in *Boulton v Bull*<sup>57</sup> more than 150 years earlier.

Thus, the High Court held that:

It is therefore a mistake, and a mistake likely to lead to an incorrect conclusion, to treat the question whether a given process or product is within the definition as if that question could be restated in the form: 'Is this a manner (or kind) of manufacture?'.<sup>58</sup>

---

<sup>53</sup> Ibid.

<sup>54</sup> Ibid, 268.

<sup>55</sup> Ibid, 269.

<sup>56</sup> Ibid.

<sup>57</sup> (1795) 126 ER 651.

<sup>58</sup> *National Research Development Corporation v Commissioner of Patents* (1959) 102 CLR 252, 269.

The Court rejected the view that 'manufacture' was confined to the production of tangible goods, simply because it is a word in everyday speech and therefore generally conveyed that idea. It continued by saying:

The right question is: 'Is this a proper subject of letters patent according to the principles which have been developed for the application of s 6 of the Statute of Monopolies?'<sup>59</sup>

After reviewing the old English case law, and the 'vendible product' test, laid down by Morton J in *GEC's Application*,<sup>60</sup> the Court pointed out that the concept of patentable subject matter has broadened and a process under consideration could be viewed within the concept of 'manufacture' notwithstanding that it merely improves, restores, or preserves some 'existing thing', provided that it offers some economical value to the country. Thus, the Court said, the test should be whether the process 'offers some advantage which is material, in the sense that the process belong to a useful art as distinct from a fine art - that its value to the country is in the field of economic endeavour.'<sup>61</sup>

It must be noted that the claims at issue were for a *process* only and there were no claims for a product. Nevertheless, the court concluded that to be patentable, an invention need not be a 'thing' in the sense of an article. The 'vendible product' test was considered wide enough to convey the broad, modern sense of this concept. Accordingly, the agricultural process was held to fall within the limits of patentability.

Since *NRDC*, the subject matter of patent may include new products, new methods, and new uses for old substances. It follows from the decision that *any* method, including method of medical treatment, could be capable of being a proper subject of letters patent, provided that it has a commercial application. The decision of the High Court received wide support and application not just in Australia but other countries as well.<sup>62</sup>

---

<sup>59</sup> Ibid.

<sup>60</sup> *In the Matter of an Application for a Patent by GEC* (1942) 60 RPC 1.

<sup>61</sup> *National Research Development Corporation v Commissioner of Patents* (1959) 102 CLR 252, 275.

<sup>62</sup> *Swift & Co v Commissioner of Patents* [1961] RPC 147; *Schering AG's Application* [1971] 3 All ER 177; *Eli Lilly & Company's Application* [1975] RPC 438; *Pharmaceutical Management Agency Ltd v Commissioner of Patents* [1999] NZCA 330; *Pfizer Inc v Commissioner of Patents* [2004] NZCA 104.

## 4.5 PATENTING OF METHODS OF MEDICAL TREATMENT

Following *NRDC*, the issue of patentability of methods of medical treatment is determined by whether the invention is 'a proper subject of letters patent according to the principles which have developed for the application of s 6 of the *Statute of Monopolies*?<sup>63</sup>

In order to answer this inquiry, it is necessary to consider two issues:

1. whether methods of medical treatment are a 'manner of manufacture' within s 6 of the *Statute of Monopolies*;
2. if they are, whether they fall within the proviso to s 6 so as to be excluded from patentability.

### 4.5.1 Issue 1: are methods of medical treatment a 'manner of manufacture' within s 6 of the *Statute of Monopolies*?

The question of whether a new method of treating the human body could be regarded as a 'manner of manufacture' and protected under Australian patent law was first directly addressed by the Full Federal Court in *Rescare*.<sup>64</sup> Before that case, there were only some *obiter* observations made by the Judges of the High Court in *Maeder v Busch*,<sup>65</sup> *NRDC* and *Joos v Commissioner of Patents*.<sup>66</sup>

#### 4.5.1.1 *Maeder v Busch*

This case was an appeal against a decision of the Supreme Court of South Australia, which had invalidated a patent for producing permanent waves in human hair by reason of prior common knowledge and prior public use. Having affirmed the judgment of the Supreme Court, all four Judges of the High Court<sup>67</sup> found it unnecessary to consider whether a claim for a new method of conducting an operation upon a part of the human body could be protected under the patent law. However, Latham CJ and Dixon J expressed doubt, by way of *obiter* comment, as to whether such methods would, in any event, constitute patentable subject matter. However, Latham CJ acknowledged the importance of the issue regarding

<sup>63</sup> *National Research Development Corporation v Commissioner of Patents* (1959) 102 CLR 252, 269.

<sup>64</sup> *Anaesthetic Supplies Pty Ltd v Rescare Ltd* (1994) AIPC 91.

<sup>65</sup> (1938) 59 CLR 684.

<sup>66</sup> (1972) 126 CLR 611.

<sup>67</sup> (1938) 59 CLR 684, 699 (Latham CJ), 707 (Dixon J) 707 (Evatt J) and 708 (McTiernan J).

patentability of methods conducting an operation on humans, and stated that the issue should not be decided 'until the necessity for doing so arises'.<sup>68</sup> For Latham CJ such a claim was quite different from a claim relating to an appliance or a substance, which might be used upon or in connection with the human body.

Dixon J also left the issue unanswered, but was prepared to consider it in some detail. After noting that to be patentable an invention must relate to an art, Dixon J questioned: 'Can the hair growing upon the human head be regarded as satisfying the condition that the process shall in some way relate to the productive arts?'<sup>69</sup> In answering this question, he referred to the case of *C & W's Application*,<sup>70</sup> and argued that it would be difficult to establish the difference between a patentable invention concerning cosmetic procedures and life-saving surgery. His Honour expressed doubts as to whether methods of treating the human body fall within the concept of invention, since 'the object is not to produce or aid the production of any article or commerce'.<sup>71</sup> This reason for this objection, however, is arguably weakened by the subsequent expansion of the meaning of 'manner of manufacture' by *NRDC*.

#### **4.5.1.2     *National Research Development Corporation v Commissioner of Patents***

This case was discussed earlier in this Chapter in relation to a manner of manufacture test.<sup>72</sup> Although the specific question concerning patentability of methods of medical treatment of the human body was not directly considered by the High Court, the judgment has significance not only because it explored and expanded the term 'manner of manufacture', but also because the interpretation of this term became wide enough to be applicable for methods of medical treatment inventions. Accordingly, provided that a method of medical treatment is useful, gives a material advantage, and is of value in the field of economic endeavour, it could potentially be a proper subject of the letters patent.

Though the High Court advocated a more flexible approach to the concept of patentable invention, it did not explore the reasoning as to whether methods of medical treatment could actually qualify. Since the invention at issue was not a method of medical treatment, the court mentioned this matter only briefly, in two passages. First, in dealing with the term 'vendible product', the High Court noted:

---

<sup>68</sup> *Maeder v Busch* (1938) 59 CLR 684, 699.

<sup>69</sup> *Ibid*, 706.

<sup>70</sup> *In the Matter of C & W's Application for a Patent* (1914) 31 RPC 235.

<sup>71</sup> *Maeder v Busch* (1938) 59 CLR 684, 706.

<sup>72</sup> See Part 4.4.2 of this Chapter.

The need for qualification must be confessed, even if only in order to put aside, as they apparently must be put aside, processes for treating diseases of the human body: see *C & W's Application*; *Maeder v Busch*.<sup>73</sup>

The word 'apparently', in the above passage has since been the object of many discussions by legal professionals, academics and judges. Graham and Whitford JJ in *Schering AG's Application*<sup>74</sup> and Witkon J in *Wellcome Foundation Ltd v Plantex Ltd*<sup>75</sup> expressed the opinion that the judges in *NRDC* must have entertained some doubt as to whether this exclusion was justified and whether or not all processes for treating the human body should be excluded from patentability. Later, Barwick CJ in *Joos*<sup>76</sup> commented 'that [passage] was no more than a passing reference not intended to be definitive.'<sup>77</sup>

On the second occasion when the High Court mentioned the issue in *NRDC*, the point was made in parenthesis:

(The exclusion of methods of surgery and other processes for treating the human body may well lie outside the concept of invention because the whole subject is conceived as essentially non-economic: see *Maeder v Busch*.)<sup>78</sup>

Again, it could be argued that by making this statement parenthetically, it was no more than a passing reference. The Court did not consider the issue of patentability of methods of medical treatment in any detail and simply dismissed the issue by relying on *Maeder v Busch* without justifying the basis for considering those methods as non-economic.

#### **4.5.1.3 *Joos v Commissioner of Patents*<sup>79</sup>**

The significance of this case lies in negating the assumption that medical or surgical processes do not have commercial application, thus narrowing the boundaries of the exclusion of these processes from patenting. The case makes it clear that the only legitimate basis on which the patentability of methods of medical treatment could be denied was public policy, which treats them as 'generally

---

<sup>73</sup> *National Research Development Corporation v Commissioner of Patents* (1959) 102 CLR 252, 270.

<sup>74</sup> [1971] RPC 337.

<sup>75</sup> [1974] RPC 514, published in Hebrew in PDI (Supreme Court Judgments), vol. 27, p 29.

<sup>76</sup> (1972) 126 CLR 611, 618.

<sup>77</sup> *Ibid*, 618.

<sup>78</sup> *National Research Development Corporation v Commissioner of Patents* (1959) 102 CLR 252, 275.

<sup>79</sup> (1972) 126 CLR 611.

inconvenient' within the meaning of s 6 of the *Statute of Monopolies*. *Joos* was the first decision in Australia where the proviso to s 6 was ever mentioned.

It is interesting to note that, three years later, the issue of public policy raised in *Joos* attracted the direct attention of the United Kingdom courts. For example, in *Eli Lilly & Company's Application*,<sup>80</sup> the Patents Appeal Tribunal, for the first time, based the exclusion of medical treatments patents on the basis of the public policy proviso to s 6 of the *Statute of Monopolies*.<sup>81</sup>

*Joos* was a successful appeal against a decision of the Deputy Commissioner of Patents, who had refused a patent to a process for improving strength and elasticity of material, especially human nails and hair. Since nails and hair were growing on the human body, the Deputy Commissioner rejected the application on the grounds that it concerned a process for the treatment of parts of the human body.

In delivering the judgment of the court, Barwick CJ stated that the appeal must be considered on the footing that the use of the process did not produce or improve a 'vendible article'. However, he held that it was not essential, and thus, not fatal to the applicant's case since *NRDC*, which was a 'watershed in this respect'.<sup>82</sup> It was enough that the process had a commercial application. Nevertheless, in the terms of *NRDC*, the question remained *whether the process claimed was a proper subject matter for the grant of letters patent* under the patents legislation.

In answering this question, Barwick CJ noted that there was no High Court authority on whether a monopoly must be refused for a process for treatment of human hair or nails whilst still attached to or growing upon the human body. For this reason, the Chief Justice distinguished *Maeder v Busch*, considering the comments in that case as *obiter* and unnecessary to the decision of the present matter.<sup>83</sup>

The Chief Justice proceeded to make a radical distinction between *treatment* of the diseases of the body and processes for improving the *cosmetic* appearance of that body. This distinction was considered important because of the implications for the question regarding a proper subject of letters patent. Accordingly, *treatment* was held to be the application to the body of a substance or process for the purpose of

---

<sup>80</sup> [1975] RPC 438.

<sup>81</sup> See discussion in Part 1.3.7 of Chapter 1.

<sup>82</sup> *Joos v Commissioner of Patents* (1972) 126 CLR 611, 617.

<sup>83</sup> *Ibid.*



arresting or curing a disease or diseased condition, or of correcting some malfunction or of ameliorating some incapacity.<sup>84</sup> Barwick CJ stated that if the process or method was in that sense of 'treatment', it was not a proper subject of letters patent.<sup>85</sup> However, Chief Justice noted that the class of such claims should be narrowly defined, and *cosmetic* processes were 'not of a like kind with medical prophylactic or therapeutic processes or methods.'<sup>86</sup> *Cosmetic* processes were held to be simply processes and methods for improving, or changing the appearance of the human body or part of it, and so were not within the narrow exception to patentability.<sup>87</sup>

Barwick CJ clarified that there may be 'borderline instances' where it would be difficult to determine whether process constitutes medical or cosmetic treatment.<sup>88</sup> Since the process at issue was clearly cosmetic, it was allowed to proceed. For the same reason, Barwick CJ was not concerned to discuss in depth a basis for the exception of methods of medical treatment. However, the Chief Justice made the following comment in relation to exception of methods of medical treatment from patenting:

If I had to do so, as at present advised, I would place the exception, if it is to be maintained, *on public policy* as being, in the language of the *Statute of Monopolies*, 'generally inconvenient'...<sup>89</sup>

(*Emphasis added*)

Considering the question whether methods of medical treatments are a 'manner of manufacture', it is submitted that the above passage could be interpreted in such a way that, if public policy could be put aside, such methods should be considered as a 'manner of manufacture' within the meaning of *NRDC* and the *Statute of Monopolies*.

The decision in *Joos* is significant for the question of patentability of methods of medical treatment. First, following *NRDC*, Barwick CJ confirmed that it was enough that the process had a commercial application, without producing or improving a 'vendible product', and concluded that most surgical and medical processes do satisfy the economic element of invention. Second, the decision narrowed down the ambit of the exclusion of methods of medical treatment, in finding that the

---

<sup>84</sup> Ibid, 619.

<sup>85</sup> Ibid.

<sup>86</sup> Ibid, 623.

<sup>87</sup> Ibid.

<sup>88</sup> Ibid.

<sup>89</sup> Ibid, 623 (*Emphasis added*).

exclusion of such methods must be based on public policy grounds. This was the first time when, in considering medical treatment inventions, the proviso to s 6 was ever referred to.

It seems that Barwick CJ's decision was influenced by the decisions of the United Kingdom Patent Office, in particular, the decision in *Schering AG's Application*,<sup>90</sup> discussed in detail in Chapter 1. In that case, as in *Joos*, a narrow view was taken as to the meaning of medical treatment, with the emphasis on the element of disease prevention. However, as pointed out, Barwick CJ in *Joos* felt that there might be difficult borderline cases.

#### **4.5.1.4 Conclusion regarding Issue 1**

In answering the question whether a method of medical treatment invention is 'a proper subject of letters patent according to the principles which have developed for the application of s 6 of the *Statute of Monopolies*?',<sup>91</sup> it is necessary to consider the first issue of whether the alleged method of medical treatment is a 'manner of manufacture' within s 6 of the *Statute of Monopolies*. Following the High Court decisions in *NRDC* and *Joos*, the answer is clearly in the affirmative, providing that the method belongs to a useful art as distinct from a fine art and has an economic value to the country. The recent decision of the Full Federal Court in *BMS*<sup>92</sup> confirmed that this could be so.

#### **4.5.2 Issue 2: do methods of medical treatment fall within the proviso to s 6 so as to be excluded from patentability?**

Before methods of medical treatment inventions would be generally considered to be 'proper subject of letters patent' the second issue must be answered in negative.

Since 1624 the courts have been empowered by s 6 of the *Statute of Monopolies* to consider whether the patenting of alleged invention is 'not contrary to the law or mischievous to the State by raising prices of commodities at home, or hurt of trade, or generally inconvenient'. However, as the previous discussion of the case law shows, until *Joos* this provision was never a factor in considering the basis for the exclusion of methods of medical treatment from patenting. The courts appeared to be comfortable with the long established grounds for such exclusion, based on the

---

<sup>90</sup> [1971] RPC 337.

<sup>91</sup> *National Research Development Corporation v Commissioner of Patents* (1959) 102 CLR 252, 269.

<sup>92</sup> *Bristol-Myers Squibb Co v F H Faulding & Co Ltd* [2000] FCA 316.

decision of *C & W's Application*<sup>93</sup>, that such inventions lacked of 'commercial value'.<sup>94</sup> The decision in *Joos* had removed that ground, but offered a new one - the forgotten 'generally inconvenient' proviso to s 6.<sup>95</sup>

However, given the ambiguous remarks of Barwick CJ,<sup>96</sup> and the statement that the Commissioner ought only to refuse to grant a patent if 'on no reasonable ground' the claimed invention could be within the Statute,<sup>97</sup> the Australian Patent Office began granting patents for methods of medical treatment, leaving any question of invalidity to be handled by the later infringement litigation.<sup>98</sup>

Nevertheless, since *Joos*, opponents to the patentability of methods of medical treatment in Australia have heavily relied on that proviso, arguing that granting a patent to such a method will be 'generally inconvenient' within the patent legislation, and therefore must be excluded from patentability. However, to date, Australian courts have been unpersuaded that public policy is a sufficient ground to justify such exclusion.<sup>99</sup> The first case in which the issue of 'general inconvenience' was put before the courts was *Rescare*.

#### 4.5.2.1 *Anaesthetic Supplies Pty Ltd v Rescare Ltd*<sup>100</sup>

This case involved patent infringement and revocation proceedings concerning an invention comprising of a device for treating snoring sickness and a method for its treatment. The inventor was Professor Colin Sullivan of the University of Sydney, who had undertaken research in the field of respiratory medicine and sleep disorders, especially, obstructive sleep apnoea (*OSA*). *OSA* is a syndrome associated with an extreme form of snoring with the high risk of repeatedly choking on the sufferer's tongue and soft palate whilst asleep. The problem could result in severe fragmentation of sleep and in an extreme case, asphyxia. The disease is a recognized cause of 'unexpected' death. Since the invention was likely to alleviate *OSA*, it was clearly for public benefit and had economic value for the country.

---

<sup>93</sup> (1914) 31 RPC 235.

<sup>94</sup> (1914) 31 RPC 235.

<sup>95</sup> *Joos v Commissioner of Patents* (1972) 126 CLR 611, 623.

<sup>96</sup> For instance, the Chief Justice used the phrases such as 'for the purpose of the decision of this case' (at 619), 'if it be accepted' (at 622), 'may be taken as an inappropriate' (at 623), and 'if it is to be maintained' (at 623).

<sup>97</sup> *Joos v Commissioner of Patents* (1972) 126 CLR 611, 615.

<sup>98</sup> David Kell, 'Comments: Expanding the Frontier of Patentability: Methods of Medical Treatment of the Human Body' (1995) 4 *European Intellectual Property Review* 202, 203.

<sup>99</sup> *Anaesthetic Supplies Pty Ltd v Rescare Ltd* (1992) 25 IPR 119; *Bristol-Myers Squibb Co v F H Faulding & Co Ltd* [2000] FCA 316.

<sup>100</sup> (1994) 50 FCR 1.

The patent was granted in 1982. The complete specification, lodged by Professor Sullivan, comprised 11 claims and described the invention as relating to apparatus for the treatment of OSA. Claims 9 and 11 were, on their face, method of process claims, as they addressed a method of treating OSA.

Rescare Ltd was the registered proprietor of the patent. It sued Anaesthetic Supplies Pty Ltd for infringement of its patent. At the trial, Anaesthetic Supplies Pty Ltd denied infringement and cross-claimed revocation of the patent on a number of grounds, including that claims 9 and 11 were not patentable subject matter, as they were directed to a method of medical treatment of the human body, 'something outside the concept of 'manner of manufacture''.<sup>101</sup>

#### (a) The judgment of Gummow J of the Federal Court of Australia

At the first instance Gummow J held that claims 9 and 11 were not directed to unpatentable subject matter. His Honour referred to Barwick CJ's statement in *Joos* that an exclusion of methods of medical treatment patents should be based on the public policy considerations of treating them 'generally inconvenient'. While accepting that the 'general inconvenience' was one of the tests under the 1952 and the 1990 Acts, and also that the question at issue should have been approached in the manner propounded in *Joos*, Gummow J was of the opinion that the judgment of Davison CJ of the Supreme Court of New Zealand in *Wellcome Foundation Ltd v Commissioner of Patents*<sup>102</sup> had the advantage of greater cogency and was closer to that of Barwick CJ in *Joos*.<sup>103</sup>

By rejecting Anaesthetic Supplies' submission that claims 9 and 11 were 'generally inconvenient' within the *Statute of Monopolies*, Gummow J held that under the patent statute there was no normative distinction to be drawn between processes for treatment of the human body for disease, malfunction or incapacity and for cosmetic processes.<sup>104</sup>

---

<sup>101</sup> *Anaesthetic Supplies Pty Ltd v Rescare Ltd* (1992) 25 IPR 119, 124.

<sup>102</sup> [1979] 2 NZLR 591 (where the Chief Justice stated that it would be an illogical result if *products* for treatment of the human body were patentable and *methods* for treating were not).

<sup>103</sup> *Anaesthetic Supplies Pty Ltd v Rescare Ltd* (1992) 25 IPR 119, 149. See discussion of *Wellcome Foundation Ltd v Commissioner of Patents* [1979] 2 NZLR 591 in Part 3.4.2.3 of Chapter 3. In that case Davison CJ questioned the justification in law and/or in logic of granting patents for substances that produce a cosmetic result and refusing patents for those that are of a curative result.

<sup>104</sup> *Ibid*, 151.

**(b) The majority decision of the Full Court of the Federal Court**

On appeal, the Court confirmed Gummow J's reasoning. By a 2-1, the majority (per Lockhart and Wilcox JJ) the Court held that methods of medical treatment were patentable under the Australian law.<sup>105</sup> However, whilst all three Judges agreed that 'general inconvenience' and the public policy considerations are relevant when determining patentability by means of the proviso to s 6 of the *Statute of Monopolies*, only Lockhart and Sheppard JJ accepted that it is within the court's competence to consider this matter. Wilcox J, on the other hand, was of the opinion that the courts 'have no special expertise' on the matters of 'ethics and social policy'.<sup>106</sup>

Lockhart J delivered the leading judgment. After an examination of the cases in Australia, New Zealand, the United Kingdom, Canada, the USA, Germany and Israel, his Honour acknowledged that some people have a deep feeling that the art of the physician or surgeon in alleviating human suffering does not belong to the area of economic value or trade and commerce.<sup>107</sup> Nevertheless, Lockhart J was of the opinion that the resolution of this question involved a 'balancing exercise' where, on the one hand, there is 'a need to encourage research in connection with methods of medical treatment' and, on the other hand, 'the need not unduly to restrict the activities of those who engage in the therapy of humans'.<sup>108</sup>

His Honour expressed the view that '[o]n both humanitarian and economic grounds the search for medical advance is to be encouraged'.<sup>109</sup> Although admitting existence of the general inconvenience argument against patentability of methods of medical treatment, Lockhart J found this argument unpersuasive. He agreed with the decision of Davison CJ of the Supreme Court of New Zealand in *Wellcome*, and concluded that there was 'no justification in law or in logic' to say that because substances produce a cosmetic or functional result as opposed to a curative result, one is patentable whereas the other is not.<sup>110</sup>

Lockhart J was of the opinion that justification for granting patent protection for processes of medical treatment based on the fact that there would be less

---

<sup>105</sup> Though the patent was held invalid on technical grounds, namely that there was no sufficient description of the invention in the provisional specification, and so the claims could not be fairly based upon that specification.

<sup>106</sup> *Anaesthetic Supplies Pty Ltd v Rescare Ltd* (1994) 50 FCR 1, 45.

<sup>107</sup> *Ibid*, 18.

<sup>108</sup> *Ibid*, 16.

<sup>109</sup> *Ibid*.

<sup>110</sup> *Ibid*, 19.

incentive to expend time, effort and money to make discoveries of new medical uses for known chemicals, if no financial return (by means of patents) was to be available.<sup>111</sup> Moreover, his Honour noted that there was no binding precedent in Australia on patentability of methods of medical treatments, and could see no reason why a method of treatment of humans was any less a manner of manufacture than a method for ridding crops of weeds as in *NRDC*.<sup>112</sup> In conclusion, his Honour propounded:

Australian courts must take a realistic view of the matter in the light of current scientific development and legal process; the law must move with changing needs and times.<sup>113</sup>

In deciding whether the application at issue was a proper subject of letters patent, Lockhart J was of the opinion that the court must adopt the test used in *NRDC*. His Honour held that the test was no more than whether the invention was a proper subject of letters patent according to the principles developed for the application of s 6 of the *Statute of Monopolies*. He felt no hesitation in declaring that the application was a proper subject of letters patent, and noted that no statutory provision in Australia prohibited the grant of a patent for a process of medical treatment of humans. Moreover, Lockhart J found it important that the Parliament had the opportunity to exclude such methods when it enacted the 1990 Act, but limited the exclusion to s 18(2).<sup>114</sup>

Wilcox J agreed generally with Lockhart J on the point of patentability of methods of medical treatment and decided the case on the issue of 'fair basing'. He rejected the appellant's argument that the law does not permit to grant a patent in respect of such methods.<sup>115</sup> His Honour also found it noteworthy that the Australian Parliament had not been persuaded by the public policy arguments against patentability, and never excluded methods of human treatment from patentability or the definition of 'invention'<sup>116</sup> (as the Parliament of the United Kingdom had done).<sup>117</sup> For these reasons, he believed that in the face of apparently *deliberate decisions by Parliament not to build this particular exclusion into its legislation*,

---

<sup>111</sup> Ibid, 18.

<sup>112</sup> Ibid.

<sup>113</sup> Ibid, 19.

<sup>114</sup> Section 18(2) provides: "Human beings and biological processes for their generation, are not patentable inventions".

<sup>115</sup> *Anaesthetic Supplies Pty Ltd v Rescare Ltd* (1994) 50 FCR 1, 42.

<sup>116</sup> Ibid.

<sup>117</sup> See Patents Act 1977 (UK), s 4(2).

'courts should be hesitant to introduce the exclusion by reference to those very general principles.'<sup>118</sup>

**(c) The dissenting judgment of Sheppard J**

Sheppard J strongly dissented in *Rescare* on the point that to grant a patent to the methods of medical treatment would be 'generally inconvenient' within the public policy proviso to s 6 of the *Statute of Monopolies*. Unlike Lockhart J (who considered the appeal decision of the New Zealand *Wellcome*, but relied on the decision of Davison CJ), Sheppard J followed the New Zealand Court of Appeal, which overturned Davison CJ's decision and held that the treatment of human illness or disease was not a manner of manufacture as it is viewed to be 'generally inconvenient', and thus could not be patented.

Central to his Honour's decision was the idea of not granting a monopoly over a surgical procedure, which might be 'greatly beneficial to mankind'.<sup>119</sup> Such monopoly, he pointed out, might mean the 'death or unnecessary suffering of countless people'.<sup>120</sup> Sheppard J pointed out that all professions develop by research and teaching. Since there is a willingness on the part of members to share information about new discoveries and new methods of treatment, 'the process is an on-going one' in which members of the medical profession learn as they go along and thus develop and improve the quality of medical treatment in the community.<sup>121</sup> The most important research and discoveries, he said, are disseminated through papers, articles, text books or conferences. Sheppard J concluded that, even though the subject matter concerning medical treatments might have 'its commercial elements', nevertheless it involves 'the treatment and relief of human suffering' and thus 'has a direct bearing on the well being of the nation'.<sup>122</sup>

By holding that the grant of a patent to an invention at issue would be 'generally inconvenient', Sheppard J said:

It is not going too far, I think, to say that the Court should not contemplate the grant of letters patent which would give to one medical practitioner, or perhaps a group of medical practitioners, a monopoly over, for example a surgical procedure which might be greatly beneficial to mankind. Its denial might mean the death or

---

<sup>118</sup> *Anaesthetic Supplies Pty Ltd v Rescare Ltd* (1994) 50 FCR 1, 43.

<sup>119</sup> *Ibid.*, 41.

<sup>120</sup> *Ibid.*

<sup>121</sup> *Ibid.*

<sup>122</sup> *Ibid.*

unnecessary suffering of countless people. I cannot think that this is really what the medical profession as a whole would seek to achieve. Its whole history is a denial of the proposition.<sup>123</sup>

In concluding that the invention did not concern patentable subject matter, Sheppard J did not base this conclusion on *NRDC* principles. Rather, his Honour considered it relevant to the issue of 'general inconvenience'.

**(d) The main points about *Rescare* case**

The decision of the Full Court was the first Australian case in which it was decided that there is nothing intrinsically unpatentable about a method of medical treatment. Prior to this decision, there had been clear indications that such methods were patentable in the United States. Similarly, in the Israeli decision in *Wellcome Foundation Ltd v Plantex Ltd*,<sup>124</sup> the Supreme Court upheld the patent for a use of a known substance in the treatment of gout.<sup>125</sup> Notwithstanding that this patent was granted under legislation prior to the new Israeli *Patents Act* 1967, which prohibited patenting of methods of medical treatment, it seems that this case significantly influenced the decision of Davison CJ in the New Zealand Supreme Court in *Wellcome Foundation Ltd v Commissioner of Patents*,<sup>126</sup> which in turn, influenced the majority of the Federal Court of Australia in *Rescare*.

Thus, at the time of the decision in *Rescare*, the matter was one free of binding authority,<sup>127</sup> and the court had to decide whether it was for the legislature or for the court to pronounce the status for methods of medical treatment patents. In terms of this issue, Sheppard J noted that the New Zealand Court of Appeal in *Wellcome*, for example, decided that if it was desirable to treat a method of medical treatment as a proper subject letters of patent, it was the task for the legislature, not the courts.<sup>128</sup> On the other hand, the Judges of the High Court in *Maeder v Busch*, *NRDC* and *Joos* concluded that the court had full capacity and power to decide this question. The only reason they did not do so 'was because no case which came before them raised the matter for decision'.<sup>129</sup> Consequently, the Federal Court in *Rescare* took the matter into its own hands, and pronounced, by majority, that methods of medical treatment are a proper subject of letters patent.

---

<sup>123</sup> Ibid.

<sup>124</sup> [1974] RPC 514, published in Hebrew in PDI (Supreme Court Judgments), vol. 27, p 29.

<sup>125</sup> See discussion of *Wellcome Foundation Ltd v Plantex Ltd* [1974] RPC 514 in Part 3.3.2 of Chapter 3.

<sup>126</sup> [1979] 2 NZLR 591.

<sup>127</sup> *Anaesthetic Supplies Pty Ltd v Rescare Ltd* (1994) 50 FCR 1, 40 (Sheppard J).

<sup>128</sup> *Commissioner of Patents v Wellcome Foundation Ltd* (1983) 1 IPR 156,172.

<sup>129</sup> *Anaesthetic Supplies Pty Ltd v Rescare Ltd* (1994) 50 FCR 1, 40 (Sheppard J).



This conclusion reaffirmed the practice of granting patents to such methods, adopted by the Australian Patent Office (**APO**) following the decision in *Joos*. However, *Rescare* did not close the debate about whether methods of medical treatment should be patentable. The strong dissenting judgment of Sheppard J indicates that disagreement in relation to this matter continued to exist. Moreover, some doubt has been cast upon the APO's practice in Heerey J's judgment in the *BMS* case of 1998.

#### 4.5.2.2 *Bristol-Myers Squibb Co v F H Faulding & Co Ltd*<sup>130</sup>

In the few years between *Rescare* and *BMS*, the position regarding patenting of methods of medical treatment remained stable and a number of patents for such methods were granted. Then, the *BMS* case, heard at the first instance by Heerey J in the Federal Court in 1998, spurred further debate over the legitimacy of such patents.

The case involved two petty patents, held by Bristol-Myers Squibb Co (**BMS Co**), for methods of dosing and administering the previously known drug taxol in the treatment of cancer. Taxol is a naturally occurring compound extracted from the bark of *Taxus brevifolia* (referred to as "Pacific yew"). At the priority date taxol was known for its anti-carcinogenic properties. However, it had been proven to cause toxic effects on patients and there were other side effects associated with its administration. The patented methods of treatment overcame these side effects by specifying the amount of taxol and the period of time for which it should be administered.

During the life of the patents, FH Faulding & Co (**Faulding**) had sold taxol to medical practitioners and hospitals around Australia along with instructions regarding its administration. Faulding also arranged clinical trials of taxol, where, before their commencement, certain protocols had been prepared.

BMS Co commenced proceedings against Faulding for infringement of its patents. Faulding cross-claimed, amongst other things, that the patents were invalid on the ground that since the invention at issue concerned methods of medical treatment of human beings, it was not a manner of manufacture, and therefore was not patentable. Faulding further cross-claimed that the invention had been published and so was not novel; did not disclose an inventive step; and was not fairly based on the matter described in the specification.

---

<sup>130</sup> [2000] FCA 316.

(a) The Judgment of Heerey J

Heerey J found in favour of Faulding on each of the cross-claims and directed that the BMS Co patents be revoked. In approaching this matter, his Honour considered whether the alleged invention fulfilled the threshold test of inventiveness and the 'pure' manner of manufacture test, in the sense of the central question discussed in *NRDC*.

His Honour first found that the invention did not satisfy the threshold requirement of inventiveness (opening words of s18(1)),<sup>131</sup> propounded by the High Court in *Philips*, by reference to the following passage:

[i]f it is apparent on the face of the specification that the quality of inventiveness necessary for there to be a proper subject of letters patent under the *Statute of Monopolies* is absent, one need go no further.<sup>132</sup>

Following *Philips*, Heerey J held that since the properties which made taxol effective against cancer were already well known, the alleged patent was not merely a claim of a new use of an old substance, but a claim for the *same* use for an old substance.<sup>133</sup> For these reasons, the alleged invention must be denied patentability.

The most controversial aspect of Heerey J's decision was his second finding, which concerned patenting of methods of medical treatment. This question was considered under the 'manner of manufacture' test. By looking at s 6 of the *Statute of Monopolies*, his Honour was of the opinion that in considering this matter, the right question that needed to be asked was 'whether the grant of a patent in these circumstances would be generally inconvenient'.<sup>134</sup>

In reaching his decision, Heerey J referred to the only Australian authority on the question of whether methods of medical treatment are patentable inventions, the *Rescare* case. His Honour was of the opinion that since the case was decided on other grounds, the views of the majority on the patentability of methods of medical treatment were *obiter* and thus not binding. Instead his Honour adopted Sheppard J's dissenting view. He considered that Sheppard J's comments on the ethics of

<sup>131</sup> See discussion of the threshold test in Part 4.3.3.1 of this Chapter.

<sup>132</sup> *NV Philips Gloeilampenfabrieken v Mirabella International Pty Ltd* (1995) 183 CLR 117, 663.

<sup>133</sup> *Bristol-Myers Squibb Co v F H Faulding & Co Ltd* [1998] 860 FCA 22, 32.

<sup>134</sup> *Ibid*, 35.

allowing patents for methods of medical treatment were equally applicable to the case at issue, since it concerned the treatment of a deadly disease, which could cause pain and distress. He commented that '[t]he present case shows in acute form the harmful effects which would follow from the granting of monopolies in respect of forms of medical treatment.'<sup>135</sup> As a result, the patenting of the alleged method was considered to be 'generally inconvenient' for public policy reasons and the two petty patents were held to be invalid.

This decision was inconsistent with the practice adopted by the Patent Office at the time, which had been granting patents to methods of medical treatment inventions since *Joos*. It is clearly inconsistent with the majority decision in *Rescare*. Arguably, if upheld, Heerey J's judgment might have had very serious implications on the development of medical research and the pharmaceutical industry in Australia.

#### **(b) The Decision of the Full Federal Court**

On appeal, the Full Federal Court found that Heerey J was in error in holding that the patents were invalid on the grounds of general inconvenience. Two judgments were delivered on appeal: a combined judgment of Black CJ and Lehane J, and that of Finkelstein J. As a starting point, Finkelstein J discussed at length the difference between *ratio decidendi* (a binding precedent) and *obiter* (a statement that is not binding). His Honour concluded that Heerey J was not free to determine for himself whether a medical process was or was not patentable subject matter and he was required to follow the majority in *Rescare* in holding that it was.

The court upheld Heerey J's findings that the BMS Co patents lacked the novelty requirement due to prior publication in Australia before the priority date. Since the novelty requirement had not been met, the Full Court held that the BMS Co patents should be revoked. Even though the patents were found to be invalid, their invalidity was found on very narrow grounds.

However, the most significant aspect of the Full Court decision was its finding, as a general principle, that methods of treatment of the human body are patentable under the 1990 Act. The court chose to deal with the issue of patentability of such methods in some detail. It unanimously overturned Heerey J's judgment on this point. The court followed the majority in *Rescare* and held that patentability of methods of medical treatment is not 'generally inconvenient'.

---

<sup>135</sup> Ibid.

- **The judgment of Black CJ and Lehane J**

Black CJ and Lehane J were influenced by two matters:

1. that in amending the 1952 Act, the Australian Parliament had chosen not to exclude methods of medical treatment of the human body from patenting; and
2. a distinction between approaches in patentability of *products* and *methods*.

In relation to the first matter, their Honours noted 'the very limited extent to which the Parliament dealt with patents with respect to the human body when it enacted the new 1990 Act.'<sup>136</sup> They emphasized that Parliament did so 'at a time when the long-standing practice in Australia was (as we are informed it still is) to grant patents for methods of medical treatment of the human body.'<sup>137</sup> The reason was based on the fact that in 1979 IPAC undertook a major review of the patent system, which resulted in replacement of the 1952 Act. In debating the new legislation, Parliament was well aware of the issues surrounding patentability of such methods. However, it choose not to follow the United Kingdom's approach of excluding methods of medical treatment from the scope of patentable subject matter, instead leaving the definition of 'invention' unchanged.<sup>138</sup>

In considering the second issue, their Honours drew attention to 'the insurmountable problem, from a public policy viewpoint, of drawing a logical distinction, which would justify allowing patentability for a *product* for treating the human body, but deny patentability for a *method* of treatment.'<sup>139</sup> In making this point, they followed Davison CJ in *Wellcome* and Gummow J in *Rescare*. Their Honours were of the opinion that since the claim was for an invention for the *administration of a product*, this case was a good example of a situation where to draw a logical distinction was impossible.

In deciding whether patenting of methods of medical treatment were 'generally inconvenient', Black CJ and Lehane J acknowledged that, at first sight, it was easy to see how it could be argued that it was 'generally inconvenient' to grant a patent to a novel life-saving therapeutic method. It would be based on a belief that such a method must be available universally and without restrictions. However, their

---

<sup>136</sup> *Bristol-Myers Squibb Co v F H Faulding & Co Ltd* [2000] FCA 316, [15]

<sup>137</sup> *Ibid*, [16].

<sup>138</sup> See *Patents Act* 1990 (Cth), s18.

<sup>139</sup> *Bristol-Myers Squibb Co v F H Faulding & Co Ltd* [2000] FCA 316, [15].

Honours did not share this view. They concentrated on logic, rather than ethics, in concluding that:

[t]he difficulty remains of drawing any logical distinction between a *method* of treatment and a patentable pharmaceutical *product* that produces the same beneficial result. More specifically, if (say) an antivenene for spider bite is patentable, on what ground can a new form of treatment for the same life-threatening bite be denied? The second consideration, referred to above [the very limited extent to which the Parliament dealt with such patents], would also seem to remain as an obstacle.<sup>140</sup>

Clearly, Black CJ and Leane J were unwilling to share the view of Barwick CJ in *Joos*<sup>141</sup> and the European decision-makers, in particular, the United Kingdom Patents Appeal Tribunal in *Eli Lilly & Company's Application*<sup>142</sup>.

While acknowledging the existence of ethical considerations, their Honours leaned towards the logical approach, based on facts mainly that patents for pharmaceutical products and medical devices have been granted for a long time, and have never been challenged on the basis of general inconvenience.

- **The judgment of Finkelstein J**

Finkelstein J examined the history of the *Statute of Monopolies* and its proviso to s 6, and concluded that the exclusion of methods of medical treatment from patenting as based on public policy grounds and, in particular, on the grounds that the grant of a patent would be illegal, mischievous to the State or generally inconvenient.<sup>143</sup>

Finkelstein J pointed out that it was necessary to make an inquiry into the scope of operation of s 6 of the *Statute of Monopolies* and the effect of its proviso. The result of that inquiry, he said, would determine whether methods of medical

---

<sup>140</sup> Ibid, [17] [Parenthesis added].

<sup>141</sup> *Joos v Commissioner of Patents* (1972) 126 CLR 611, 623. In this case Barwick CJ expressed the view that he would place the exception on "public policy as being, in the language of the *Statute of Monopolies*, "generally inconvenient"... ."

<sup>142</sup> [1975] RPC 438.

<sup>143</sup> Although his Honour looked at the history of the proviso to s 6 of the *Statute of Monopolies*, he did not consider its meaning or purpose. This thesis argues that an understanding of how the proviso, and in particular, the term 'generally inconvenient' should be interpreted by courts is important. Thus, in Chapter 5 it is argued that the modern interpretation of the term is contrary to its original meaning and, arguably, the patent law concept. Chapter 5 also makes an inquiry into whether it is correct to interpret the proviso absolutely in its strict sense - in isolation to the rest of s 6, which it qualifies.

treatment are a patentable invention.<sup>144</sup> His Honour held that methods of medical treatment clearly fell within the concept of manner of manufacture.<sup>145</sup>

The second critical question was whether medical or surgical process patents were 'generally inconvenient'. He proceeded to consider the public policy arguments for and against such patents and stated:

Perhaps the most powerful argument against patenting is the idea that a patient may be denied medical treatment that she needs. .... It presumes that a medical practitioner may be unable to obtain the right to use a particular process, or may not be able to do so within due time, and therefore will be unwilling to undertake the process on her patients for fear of legal action.<sup>146</sup>

His Honour noted the other side of the debate, that the fundamental principle of granting patents is the promotion of science and the advancement of the arts for the general welfare of the State. By approaching this counter-argument, Finkelstein J continued:

As a general principle there can be no doubt that patent protection is desirable to encourage new medicines and surgical methods. It is inescapable fact that inducement is necessary to encourage the great expense that is now required to evaluate and investigate the utility of many new medical processes and surgical methods.<sup>147</sup>

In considering the above argument Finkelstein J faced the dilemma of how the courts are to resolve these competing public policy issues, given that none of them are supported by empirical data, and, as he noted, some may not even be capable of proof. His Honour then stressed that even if there was some evidence, 'on what basis is the court to decide how the public interest will best be served?'<sup>148</sup>

In approaching this issue, Finkelstein J adopted the view taken by the Supreme Court of the United States in *Diamond v Chakrabarty*.<sup>149</sup> In that case the court was asked to decide whether a live human-made microorganism was patentable subject matter. Having faced the strong public policy argument against such patenting, the court ruled that when the process involves balancing of competing

---

<sup>144</sup> *Bristol-Myers Squibb Co v F H Faulding & Co Ltd* [2000] FCA 316, [12]. See also above n 138.

<sup>145</sup> *Ibid*, [32].

<sup>146</sup> *Ibid*, [36].

<sup>147</sup> *Ibid*, [38].

<sup>148</sup> *Ibid*, [42].

<sup>149</sup> 447 US 303 (1980).

values and interests of society, it is the task for elected representatives, such as the political branches of the Government, the Congress and the Executive, and not the courts.<sup>150</sup> By taking this view, and pointing at the limited ability of courts to take evidence on the social and economic policies involved, Finkelstein J concluded:

I do not believe that in a controversial issue such as is raised by the present argument, I would be abandoning my responsibility as a judge to follow this approach [taken in *Diamond v Chakrabarty*] and to hold that if public policy demands that a medical or surgical process should be excluded from patentability, then that is a matter that should be resolved by the Parliament.<sup>151</sup>

This view reflects Wilcox J's view in *Rescare*, who said that the courts have no 'special expertise' in matters of ethics and social policy.<sup>152</sup> It also reflects the approach (though with the opposite result) of the United Kingdom Patents Appeal Tribunal judges, Graham and Whitford JJ, in *Eli Lilly*,<sup>153</sup> Russell LJ in *Upjohn Company (Robert's) Application*,<sup>154</sup> and the New Zealand Court of Appeal in *Wellcome*.<sup>155</sup>

However, whilst casting doubt over the competency of the courts in considering the 'generally inconvenient' prohibition in s 6 of the *Statute of Monopolies*, it could not be said that Finkelstein J thought that the courts lacked 'special expertise' at all in matters of ethics and social policy. His Honour's decision goes beyond Wilcox J's view in *Rescare*. Indeed, Finkelstein J considered the public policy arguments for and against medical patents in this judgment.<sup>156</sup> It could be understood, therefore, that he was of the opinion that the proviso to s 6 should not be ignored, and thus moral considerations are still relevant to the question of patentability. By holding that medical treatment and surgical process are patentable in Australia, his Honour found that public policy considerations against patenting of methods of medical treatment were of less significance in comparison with the advantages offered by the encouragement of medical research.<sup>157</sup>

---

<sup>150</sup> *Diamond v Chakrabarty* 447 US 303 (1980), 318.

<sup>151</sup> *Bristol-Myers Squibb Co v F H Faulding & Co Ltd* [2000] FCA 316, [43] [Parenthesis added].

<sup>152</sup> *Anaesthetic Supplies Pty Ltd v Rescare Ltd* (1994) 50 FCR 1, 45.

<sup>153</sup> [1975] RPC 438, 445.

<sup>154</sup> [1977] RPC 94.

<sup>155</sup> *Commissioner of Patents v Wellcome Foundation Ltd* (1983) 1 IPR 156, 172.

<sup>156</sup> *Bristol-Myers Squibb Co v F H Faulding & Co Ltd* [2000] FCA 316, [36]-[43].

<sup>157</sup> *Ibid*, [38]-[42].

#### 4.5.3 The Effect of the Decisions in *Rescare* and *BMS* on the Australian Medical Profession

The *BMS* case represents one of the most significant decisions of the Federal Court of Australia in recent times, for it made an important contribution not only to the body of case law on patenting of medical methods, but to patent law in general. The decision provides a valuable and authoritative statement on the law concerning patentability of such methods and addresses several issues related to the interpretation of the 1990 Act, such as the meaning of the threshold test for patentability.

The decision also highlights the complexity of the combination of patent law and public policy issues. It acknowledges that consideration of moral and ethical matters in deciding what would be best for the society has been a difficult task for the courts. The decision cast doubt over the courts' competency in deciding these tasks.<sup>158</sup>

In relation to patenting of medical methods issue, *BMS* delivers a clear message that, for the time being, methods of medical treatment are patentable under the 1990 Act. However, if public policy requires a different result, it is for the Parliament to amend the legislation.<sup>159</sup> Since the parties in this case did not appeal to the High Court of Australia, the Full Federal Court decision will provide the guiding approach to the issue under consideration, and will be the binding authority for the time being, notwithstanding that the patents were declared invalid on other grounds.

It is submitted that had Heerey J's judgment in *BMS* been upheld, it might have had serious implications for the development of medical research and the pharmaceutical industry in Australia. It is highly likely that in order to continue this development the inventors would have been forced to use the Swiss-type form, which is a legal fiction, for it allows a patent protection for a method of therapeutic treatment indirectly.<sup>160</sup> However, the appeal decision clarified the issue and prevented the need for getting around the prohibition. By pronouncing methods of medical treatment patentable in Australia, the *BMS* decision gave medical researchers greater confidence that they will be able to recover high expenses associated with research.

---

<sup>158</sup> It is beyond the scope of this thesis to make an inquiry as to whether judges have ability to make moral or public policy judgments in interpreting statutes.

<sup>159</sup> *Bristol-Myers Squibb Co v F H Faulding & Co Ltd* [2000] FCA 316, [45].

<sup>160</sup> See discussion of 'Swiss-type' form in Chapter 2, Part 2.5.



The implications of *Rescare* and *BMS* for the medical profession are that the Australian Patent Office considers *any* medical invention as being a proper subject matter for letters patent. Thus, new invention such as:

- medical device;
- medical substance;
- method for using a device and/or substance;
- new use and/or method for an old substance; and
- pure method of medical treatment of the human body,

could all be considered to be 'patentable inventions' in Australia provided that they fulfil the standard patenting requirements. It is argued in this thesis that both the inventor, in this case, a medical practitioner, and the public benefit from this temporary monopoly because, during the time of a patent, the medical practitioner is able to exclude others from exploiting the invention for 20 years<sup>161</sup> and when the patent expires, the invention is freely available for others to use.

However, a disadvantage of this arrangement is that when a medical practitioner is found infringing a patent the court may grant an injunction to prevent further infringement; and, at the patent-holder's option, grant damages or an account of profits to compensate them.<sup>162</sup> Such consequences raise the important public policy concern that in order to ensure the best possible health outcomes, a medical practitioner must always be free to choose the best possible method of treatment. Since a patent may restrict this freedom, the debate still exists whether methods of medical treatment should be excluded from patent protection, or whether the US approach should be adopted, protecting medical practitioners from liability. These issues will be addressed in Chapter 6.

---

<sup>161</sup> See *Patents Act 1990* (Cth), Ss 65 and 67.

<sup>162</sup> See *Patents Act 1990* (Cth), s 122(1).

## 4.6 CONCLUSION

With the passage of the new 1990 Act, the Australian Parliament chose to leave the terminology of 'invention' and 'manner of manufacture' unchanged. It seems that the Parliament felt comfortable with the current status of the 'manner of manufacture' concept, developed by the High Court in *NRDC*. This case clearly formed the turning point in the case law development of the concept of 'manner of manufacture', and, as the other authors have commented, its general impact is similar to that of *Donoghue v Stevenson*<sup>163</sup> in the law of negligence.<sup>164</sup> The importance of the *NRDC* decision has since been recognised in all jurisdictions where the 'manner of manufacture' is or had been one of the requirements of patentability. Thus, the decision is still a part of the law of Australia<sup>165</sup> and New Zealand<sup>166</sup> and was accepted in England prior to the enactment of the new *Patents Act 1977* (UK).<sup>167</sup>

From the fact that the terminology of 'invention' and 'manner of manufacture' were left unchanged, it could be inferred that the Parliament endorsed a broad and flexible power for the courts to decide what is suitable subject matter for the grant of letters patent and, under *NRDC* principles, this decision must be made in the light of progress in the field of science and technology. Since this is a constantly evolving process, it might not, in some cases, be a straightforward task to decide whether the invention at issue is or is not a 'patentable invention' within the meaning of the 1990 Act. One example of such a case is the patentability of methods of medical treatment. Indeed, it is a complicated issue, taking into account that the definition of 'invention' provides little or no guidance as to whether such methods could be patentable subject matter, and neither the legislation nor the case law provide guidance on whether patenting of such methods would or would not be 'generally inconvenient' under the proviso in s6 of the *Statute of Monopolies*, which is a part of the definition of 'invention'.

---

<sup>163</sup> [1932] AC 562.

<sup>164</sup> William van Caenegem, 'The Technicality Requirement, Patent Scope and Patentable Subject Matter in Australia' (2002) 13 *Australian Intellectual Property Journal* 309, 310.

<sup>165</sup> *NRDC* was applied in *IBM Corporation v Smith, Commissioner of Patents* (1991) 22 IPR 417; *CCOM Pty Ltd v Jiejing Pty Ltd* (1994) 28 IPR 481; *Anaesthetic Supplies Pty Ltd v Rescare Ltd* (1994) 50 FCR 1; and *Bristol-Myers Squibb Co v F H Faulding & Co Ltd* [2000] FCA 316.

<sup>166</sup> *Swift & Co v Commissioner of Patents* [1960] NZLR 775; *Wellcome Foundation Ltd v Commissioner of Patents* [1979] 2 NZLR 591 and *Pharmaceutical Management Agency Ltd v Commissioner of Patents* [1999] NZCA 332.

<sup>167</sup> *Swift & Co's Application* [1962] RPC 37.

However, what *is now clear*, in Australia, is that methods of medical treatment are considered to be a 'manner of manufacture' within s 6 of the *Statute of Monopolies*. In considering this issue, courts have been guided by the decisions in *NRDC* and *Joos*. Although, the question of patentability of methods of medical treatment of the human body was not directly considered by the High Court in *NRDC*, it follows from that decision that any methods, including methods of medical treatment, could be capable of being a proper subject of letters patent, provided that they have commercial application. *Joos*, in its turn, removed the assumption that medical or surgical processes do not have commercial application. The decision narrowed the boundaries of the exclusion of methods of medical treatment from patenting. The case makes it clear that the only legitimate basis on which the patentability of methods of medical treatment could be denied is on public policy. This case opened debate on question of whether general inconvenience could be used to introduce public policy considerations into Australian patent law.

*Rescare* and *BMS* seem to have shut the door somewhat, at least for methods of medical treatment. However, the true ambit of general inconvenience remains uncertain and it is likely that further attempts will be made in the future to introduce public policy considerations under its veil. The next Chapter analyses the origins and history of patent law to see if there is any basis for using general inconvenience to import such public policy considerations into Australian law.

## CHAPTER 5: THE PROVISO TO SECTION 6

We have graunted to God: when anything is granted for God, it is deemed in Law to be graunted to God...And this and the like were the formers of ancient Acts and Graunts, and those ancient acts and graunts must be construed and taken as the Law was holden at that time when they were made.<sup>1</sup>

### 5.1 INTRODUCTION

As noted previously, s 18(1) of the *Patents Act 1990* (Cth) (the **1990 Act**) defines a 'patentable invention' as one that 'is a manner of manufacture within the meaning of Section 6 of the *Statute of Monopolies*'. The *Statute of Monopolies 1624* (the ***Statute of Monopolies***) declared all monopolies void, aside from the exception contained in s 6. This section defined the privileges which the Crown might grant to new inventors, and it became the foundation of present day patent law. The following is the precise wording of s 6:

Provided also (and be it declared and enacted)<sup>2</sup> that any declaration before mentioned shall not extend to any letters patent and grants of privilege for the term of fourteen years or under, thereafter to be made, of the sole working or making of any manner of new manufactures within this Realm, to the true and first inventor and inventors of *such manufactures* which others at the time of making such letters patent and grants shall not use (**main provision**), so as also they be not contrary to the law or mischievous to the state, by raising prices of commodities at home, or hurt of trade, or *generally inconvenient* (**proviso**).<sup>3</sup>

Since s 6 remains a part of Australian law by virtue of s 18(1) of the 1990 Act, when deciding whether an alleged invention is patentable, examiners and courts consider the meaning of s 6, including that of the entire proviso for manufactures that are also contrary to the law or mischievous to the state, by raising prices of commodities at home, or hurt of trade, or generally inconvenient.

---

<sup>1</sup> Edward Coke, 2 *Institutes of the Laws of England* (1644), 2, commencing with the opening phrase of Magna Carta, in D J Hurst, 'The problem of the Elderly Statute' (1983) *Legal Studies* 21.

<sup>2</sup> Words in brackets repealed by the *Statute Law Revision Act 1888* (51 Vict. C. 3), s1, Schedule. Part I.

<sup>3</sup> 21 Jac. I, c.3, § 6 (*Emphasis added*).

Therefore, in answering the question of whether a method of medical treatment of the human body is patentable, one must consider whether or not a patent for such method is 'generally inconvenient'. This leads to the enquiry as to the meaning of the term, which, in turn, cannot be ascertained without close examination of its origin and purpose.

This Chapter analyses the origins of s 6 in detail. Since the main reason for prohibiting patenting of methods of medical treatment in Australia has been based on the courts' interpretation of the proviso '*also they be not... generally inconvenient*' as a public policy clause, attention will be focused particularly on the meaning of given to this proviso in the case law and debates leading up to the *Statute of Monopolies*. This Chapter aims to challenge the modern judicial interpretation of the proviso and show that it is not supported by the ancient laws. The main proposition of this thesis regarding interpretation of 'inconvenience' is that only patents that are given to a known commodity should be void on the basis of being inconvenient or contrary to law and monopolies to new inventions *should not be declared invalid on the basis of inconvenience*.

The historical analysis in this Chapter aims to ascertain the meaning of the phrase '*also they be not... generally inconvenient*' and the role it was intended to transmit. The result of that inquiry determines whether or not it is correct to justify exclusion from patentability of methods of medical treatment based on the proviso of general inconvenience alone. Chapter 4 of this thesis illustrated that the Full Court of the Federal Court of Australia was not willing to use general inconvenience to justify exclusion of methods of medical treatment in the case of *Bristol-Myers Squibb Co v F H Faulding & Co Ltd*<sup>4</sup> (*BMS*). This thesis accepts that the decision in that case was correct, but questions the reasoning behind the application of general inconvenience. The court in *BMS* accepted that the general inconvenience proviso could be used to introduce public policy considerations in patent examinations in Australia. In this Chapter it is argued that the general inconvenience proviso was never intended to be used in this way. It is further argued that this form of usage is contrary to the general rules of statutory interpretation. It will be argued in Chapter 6 of this thesis that if it is desirable to introduce such considerations then it should be done overtly, and not under the guise of general inconvenience.

---

<sup>4</sup> [2000] FCA 316.

## 5.2 HISTORY OF THE PROVISIO TO SECTION 6 OF THE STATUTE OF MONOPOLIES

### 5.2.1 Pre-Enacting History

#### 5.2.1.1 Letters Patent

The name 'letters patent' is derived from the Latin *litterae patentes*, which means 'open letters'.<sup>5</sup> Originally these documents were executed by English sovereigns and meant to be read without the need of breaking their seals. They were intended to be open to the public and traditionally began: 'To all to whom these presents shall come.'<sup>6</sup>

These letters patents had nothing to do with inventions per se, but represented privileges to promote royal policies. The English sovereign was empowered with certain prerogatives that allowed him<sup>7</sup> to give various freehold interests, franchises and other privileges upon favored subjects. He granted those privileges 'for the sake of the public good, although prima facie they appear to be clearly against common right.'<sup>8</sup> The sovereign usually granted letters patents only upon receipt of consideration. The validity of such grants was recognised by the medieval lawyers if they could be shown to be clearly for the welfare of the realm.<sup>9</sup> This was due to shortage of the ready cash needed to operate the monarchs' respective administrations. Such grants were accomplished by the letters patent so that every one could see the favored subject.<sup>10</sup>

Thus, through the exercise of the royal prerogative, letters patents were used for appointment of military, judicial and colonial officers, and to confer rights, privileges, ranks or titles personally and directly from the sovereign. They were recorded on the Patent Rolls in the Record Office.<sup>11</sup>

---

<sup>5</sup> R A Klitzke, 'History of Patents Abroad' in R Calvert, *The Encyclopedia of Patent Practice and Invention Management* (1964), 384.

<sup>6</sup> Gomme, *Patents of Invention*, (1946), 1

<sup>7</sup> Here, the male form is used because sovereigns almost invariably were male at the time.

<sup>8</sup> EW Hulme 'The History of the Patent System Under the Prerogative and at Common Law' (1896) 12 *Law Quarterly Review* 141,143, continued at (1900) 16 *Law Quarterly Review* 44.

<sup>9</sup> W Holdsworth, *A History of English Law* (3<sup>rd</sup> ed, 1945) vol 4, 345.

<sup>10</sup> Maitland, *The Constitutional History of England* (1950), 260.

<sup>11</sup> Klitzke, above n 5, 384.

### 5.2.1.2 Early English industrial grants and meaning of 'invention'

English patent law made greater advances in the Tudor period than in any other. The Sixteenth century could well be called 'the birth years of the English patent system'.<sup>12</sup> In pursuing national economic policy of stimulating domestic production of both raw materials and manufactured goods previously imported from abroad, in 1561 Queen Elizabeth I introduced the new system of granting industrial monopoly licences. This system is considered to be the origin of our modern patent law.<sup>13</sup>

It must be noted that although the term 'invention' was used at the time, the meaning of invention was different from its modern meaning. For instance, E Wyndham Hulme explains that the word 'invention' denoted mainly the physical act of introducing, rather than the mental process of 'discovering'.<sup>14</sup>

Early English patents for inventions were, in fact, patents for the introduction of a new 'trade' rather than for 'invention' in the modern sense. These types of patents, although distinguished from other patents, were thought and spoken of in terms of a policy strategy used to nourish and support the development of the English economy by the introduction of a new trade and industry.

Statistics for the periods 1561-1603 indicate that Queen Elizabeth I granted 55 monopoly licences, 21 of which to foreign inventors for new industries and inventions.<sup>15</sup> The essence of the industrial monopoly licences was that, in return for the introduction of an unknown manufacturing process, the introducer was granted a monopoly of using that process for a specified period.

### 5.2.1.3 Clauses to secure the fulfillment of the promise by the grantee

In the absence of any requirement to describe the nature of the invention and the best method for performing it, the Crown needed to do something to prevent foreign inventors 'from suddenly returning home before the termination of their periods of privilege without having established the new industries which they

---

<sup>12</sup> Klitzke, above n 5, 389.

<sup>13</sup> Holdsworth, above n 9.

<sup>14</sup> EW Hulme 'The History of the Patent System Under the Prerogative and at Common Law' (1896) 12 *Law Quarterly Review* 141, 151.

<sup>15</sup> EW Hulme, 'The History of the Patent System Under the Prerogative and at Common Law' (1900) 16 *Law Quarterly Review* 44, 52.

premised to introduce.<sup>16</sup> History has shown that, at that time, there were instances that the Crown was deceived in this way.<sup>17</sup>

Such deception resulted in a requirement to include in patent grants clauses to secure the fulfillment of the promise by the grantee. By virtue of these clauses the grantees were required to introduce their processes within a fixed period of time, to employ and teach English subjects, and sometimes to manufacture a minimum quantity within a given time.<sup>18</sup> It is submitted that these clauses may provide some insight on the uncertainty around the meaning of 'generally inconvenient' in s 6. For this reason, they require a detailed examination.

#### **(a) Limitation of time clause**

The first type of clause inserted in the grant was a limitation of time. By virtue of this clause a patentee was obliged to introduce his<sup>19</sup> invention to the realm, and /or prove that it was new and useful. Failure to fulfill this condition resulted in avoidance of the grant.<sup>20</sup> Some examples of relevant clauses include the following:

- Cockeram's patent (1561)<sup>21</sup> - 'one year - void if "not of the utility and profit as is presently pretended"';
- Cobham (1562)<sup>22</sup> - 'three months';
- Stoweberghen (1563)<sup>23</sup> - 'the grant is void in case the patentees fail to come over and put the grant into practice within two months';
- Burchard Cranick (1563)<sup>24</sup> - 'three years... to demonstrate his said arte to be perfitt and unfaylable and that also the like thereof hath not bene put into execution within this our Realm'; and
- Peter Morris (1578)<sup>25</sup> - 'three years'.

---

<sup>16</sup> D Seaborne Davies, 'The Early History of the Patent Specification' (1934) 50 *Law Quarterly Review* 86, 100.

<sup>17</sup> Ibid.

<sup>18</sup> Holdsworth, above n 9.

<sup>19</sup> Here, the male form is used because almost in every occasion the inventors were male at the time

<sup>20</sup> Davies, above n 16.

<sup>21</sup> P.R. 3 Elizabeth, 6.

<sup>22</sup> P.R. 4 Elizabeth, 10.

<sup>23</sup> P.R. 5 Elizabeth, 1.

<sup>24</sup> P.R. 5 Elizabeth, 2.

<sup>25</sup> P.R. 20 Elizabeth, 10.



## **(b) The apprenticeship clause**

The apprenticeship clause is another device used during the reign of Elizabeth I to secure the consideration for the grant. The apprenticeship clause provided that the grantee should teach their 'art and science', their 'feat and mystery', to Englishmen.<sup>26</sup> For instance, the monopoly patent granted to Cockeram in (1561),<sup>27</sup> in addition to the abovementioned limitation of time clause, required that at least two of the patentee's workers were to be of 'native birth'.<sup>28</sup> The patent to Becku and Carre' (1567)<sup>29</sup> for the manufacture of window glass demanded as a condition for the validity of the patent that the French patentees train Englishmen in this trade.<sup>30</sup>

The apprenticeship clause is also found in the patents granted during the reigns of James I and Charles I,<sup>31</sup> and was reproduced in different forms in patents granted after the *Statute of Monopoles* and Restoration.<sup>32</sup>

The fact that the above clause was also a condition that authorised the Crown to declare grants void on proof of its non-fulfillment suggests that it fell into the wide term of 'inconveniency' in addition to a limitation of time clause.

## **(c) The 'inconveniency' proviso (1575)**

The limitation of time clause gradually transformed into a revocation clause that authorised Elizabeth I to declare grants void on proof of their inconveniency. According to Professor Seaborne Davies, 'inconveniency' was 'a proviso' and 'a wide term which cover any failure to introduce an invention within a reasonable period'.<sup>33</sup> For the first time this proviso was inserted in the grant of a letters patent to Holmes and Frampton for African Headwear (1575).<sup>34</sup> It was generally used after that, particularly during the period of debate against Monopolies in Parliament in 1601. Examples can be found in the patent to Nasmith<sup>35</sup> and many others. In its

---

<sup>26</sup> Davies, above n 16.

<sup>27</sup> P.R. 3 Elizabeth, 6.

<sup>28</sup> Hulme, above n 14, 145.

<sup>29</sup> P.R. 9 Elizabeth, 11.

<sup>30</sup> Hulme, above n 14, 149.

<sup>31</sup> Davies, above n 16.

<sup>32</sup> Ibid. The period of Restoration refers to the return of a constitutional monarchy to Great Britain in 1660 under Charles II, in particular, the period between the crowning of Charles II and the Revolution of 1688.

<sup>33</sup> Davies, above n 16.

<sup>34</sup> P.R. 17 Elizabeth, 9.

<sup>35</sup> P.R. 10 Anne, 2.

final form the proviso stated that 'if on examination of the patent the grant was found to be *inconvenient or prejudicial to the realm*, the patent immediately, or at the end of a specified period of notice, was to be void and frustrate'.<sup>36</sup>

Hyde Price stated that in the course of the agitation against Monopolies in 1601, many patents were brought to trial and at least 15 had been revoked on basis of the 'inconveniency' proviso.<sup>37</sup> To illustrate this point, in 1601 one member of the Parliament, Sir Robert Wroth argued:

And I have heard a Gentleman affirm in his House [the Court of Exchequer] that there is a Clause or Revocation in these Patents; if so what needed this stir of Scire Facias, Quo Warranto and I know not what, when it is but only to send for the Patentees and cause a redelivery?<sup>38</sup>

The above indicates that the patent would be found to be inconvenient if the underlying invention failed to be introduced by the grantee within specified period in the grant.

It will be demonstrated further in this Chapter that as the consequence of numerous debates in the Parliament during 1623 and 1624, this proviso became a permanent feature of s 6 of the *Statute of Monopolies*, which played role of a general escape clause. According to Hulme, Price and Davies, this escape clause appeared often in the patents of James I.<sup>39</sup> During the next 100 or so years there were some periods when it was omitted, but Davies argues that the Privy Council frequently declared the patents void under this clause throughout the seventeenth century, and that there are records of patent revocations made under the clause as late as 1779.<sup>40</sup>

#### **5.2.1.4 Conclusion regarding 'limitation of time' and 'apprenticeship' clauses**

It follows that limitations of time and apprenticeship clauses were the main devices used by the Crown to ensure that the promise of the grantee would be fulfilled. These revocation clauses were general escape clauses that gave the Crown or the Privy Council a power to revoke a patent upon proof of inconveniency. On this basis the author submits that these clauses formed the principal components of the

---

<sup>36</sup> Davies, above n 16.

<sup>37</sup> W Hyde Price, *The English Patents of Monopoly* (1913), vol 1, 20-22 and Appendices H, J and I.

<sup>38</sup> Townsend's Historical Collection, 225; S. P. D., Elizabeth, CCLXXXII, 28, 65-67.

<sup>39</sup> Hulme, above n 15; Price, above n 37; Davies, above n 16, 100.

<sup>40</sup> Davies, above n 16, 100.

wider revocation clause of 'generally inconvenient' in s 6 of the *Statute of Monopolies*.

It is important to note that some grants specified other *particular forms of inconveniency* in addition to limitation of time and apprenticeship. These forms included that the patent 'crossed' some previous grant,<sup>41</sup> or lacked novelty, or that the patentee was not the first inventor, or that the invention was not useful.<sup>42</sup> It is concluded that these particular forms of 'inconveniency' also formed part of the foundation of the proviso, and therefore they are worthy of consideration.

## 5.2.2 Particular forms of 'inconveniency' - the invention must be new and useful

### 5.2.2.1 *Matthey's case* (1571) and *Bircot's case* (1572)

The requirement that the patent cannot be 'inconvenient' was specified in the requirement that a patent could only be given to a new manufacture. The main idea or policy behind this was to prevent displacing an existing trade within the realm.<sup>43</sup>

Accordingly, a patent was treated 'inconvenient' if it was given to an already known trade, or a mere improvement. For example, this issue was central to a dispute in 1571 before the Privy Council regarding the monopoly patent granted to Rd. Matthey to make 'Turkye haftes' for knives (*Matthey's case*).<sup>44</sup> Another case regarding a patent for mere improvements was *Bircot's case* (*Bircot's case*).<sup>45</sup> Although these cases were never reported,<sup>46</sup> they were frequently cited until the late eighteenth century as authorities for opposing patenting of improvements of existing manufactures. *Matthey's case* is known from its inclusion in submissions of counsel for Allen - Mr Fuller - in the famous case of *Darcy v Allen*<sup>47</sup> (*Darcy v Allen*). *Bircot's case* is known mainly from Sir Edward Coke's reference in his *Institutes of the Laws of England*.<sup>48</sup>

*Matthey's case* was decided in the Privy Council and involved a patent for manufacture of knives with a new kind of hafts. According to reference made to this

---

<sup>41</sup> Nasmith, P.R. 10 Anne, 2.

<sup>42</sup> See Council Registers, Vol 71, 276; Vol 72, 484; Vol 75, 267etc, listed by Davies, above n 16, 103.

<sup>43</sup> Hulme, above n 15, 56.

<sup>44</sup> Hulme, above n 15, 45.

<sup>45</sup> Edward Coke, 3 *Institutes of the Laws of England* (1644) 181, 183.

<sup>46</sup> Charles Viner, *A General Abridgment of Law and Equity* (2nd ed, 1793), 210-11 (citing *Matthey's case*, Noy 113).

<sup>47</sup> (1603) Noy 173-185, 74 ER, 1131, 11 Co Rep 84b-88b, 77 ER, 1260.

<sup>48</sup> Coke, above n 45 181, 183.

case by Mr Fuller in *Darcy v Allen* and Charles Viner's summary of the case, the patent was granted to Matthey for the sole making of knives with bone hafts and plates of latin.<sup>49</sup> The wardens of the company of cutlers argued that 'they did use to make knives before, though not with such hafts; and that such a light difference or invention should be no cause to restrain them'.<sup>50</sup> The wardens further argued that the patent was for 'mere improvements' and was already known in the realm at the time of the grant. Therefore, it was submitted that the patent was inconvenient and no one could benefit from it. This argument was accepted by the Privy Council who ruled that the new hafts were 'mere improvements' and thus did not justify the patent. Consequently, the Privy Council declared the patent void on basis of its inconveniency.

*Bircot's case*<sup>51</sup> is another example of a patent for 'mere improvements'. According to Coke, the patent concerned a new method of preparing and melting of lead ore. In that case, the patent was held to be contrary to law because the invention in question was not a new manufacture, but rather it was like putting 'a new button on an old coat'.<sup>52</sup>

#### **5.2.2.2 Conclusion regarding *Matthey's* and *Bircot's* cases**

In the absence of the case reports it is impossible to ascertain the exact explanation of 'inconvenience'. The extent of restraint to which the judgments were laid on royal prerogative for inconvenient patents also remains unclear. However, the references to these cases suggest a possible legal basis for the revocation clause of 'generally inconvenient', which appeared later in s 6 of the *Statute of Monopolies*.

At the very least, the information that we have on these cases give an indication as to what arguments were relied upon to show that a monopoly was inconvenient. Though the introduction of new technologies means that the rule against improvements of existing manufactures propounded in these cases is no longer relevant, *Matthey's* and *Bircot's* cases should be viewed in the context of the conceptual environment at the time, wherein inventions were viewed in terms of the introduction of pure new manufactures or trades to the realm. The rule against improvements was based on policy that, although in some cases technological advances could be desirable and beneficial, in other cases 'mere improvements' of

---

<sup>49</sup> Viner, above n 46.

<sup>50</sup> Ibid.

<sup>51</sup> Coke, above n 45, 183.

<sup>52</sup> Ibid.

existing manufactures could be inconvenient and harmful.

According to Edward Waterscheid, the rule against improvements was usually employed to argue that the proposed benefit involved with the introduction of a monopoly patent for an improvement to an existing trade was likely to be much smaller than the harm that would be caused by such a monopoly to the realm, such as the employment and livelihoods of Englishmen.<sup>53</sup> Coke explains this in the following way: '...a mans trade is accounted his life, because it maintaineth his life; and therefore the monopolist that taketh away a mans trade, taketh away his life, and therefore is so much the more odious.'<sup>54</sup>

*Matthey's* and *Bircot's* cases demonstrate that patent monopoly could only be granted to a new trade, or a trade that had not existed within the realm in recent memory<sup>55</sup> - granting a monopoly otherwise would unlawfully restrain someone's trade and be harmful to the realm, thus causing inconvenience. Moreover, *Matthey's* case illustrates the point that to be 'convenient' a monopoly must not only be given to a new manufacture but must also be beneficial for the realm.

It is important to emphasise that there was no suggestion in the cases that if letters patents simply purported to restrain subjects from engaging in a trade, they had to be void for inconveniency. The cases show the common law position, which was quite opposite - if an invention was in relation to a *lawful* trade or manufacture, which was new, or given to a first inventor, it would be granted a monopoly patent. That would be the case notwithstanding that the monopoly would restrain subjects from unauthorised practising of this trade for a certain period.<sup>56</sup>

This position was reaffirmed in *Darcy v Allen*. In support of his proposition that Darcy's patent was unlawfully restraining someone's trade, Mr Fuller referred to the *Matthey's* case. Though the term 'inconvenience' was never used in his submissions, it seems that Fuller was suggesting that the patent should be viewed as contrary to the law or inconvenient if it is given to a known commodity.<sup>57</sup> The full import of *Darcy v Allen* will be discussed in the next section.

---

<sup>53</sup> Edward C. Walterscheid, *The Early Evolution of the United States Patent Law: Antecedents*, (4 parts), (1994) 76 *Journal of the Patent Office Society* 697, 849 (parts 1-2); (1995) 77 *Journal of the Patent Office Society* 771 (part 3); (1996) 78 *Journal of the Patent Office Society* 71 (part 4).

<sup>54</sup> Coke, above n 45, 183.

<sup>55</sup> Hulme, above n 15, 56.

<sup>56</sup> This conclusion undermines the legitimacy of the main argument against patents for methods of medical treatment, which based on the proposition that since such patents might restrict physicians from practicing their medical practice, the patents are inconvenient.

<sup>57</sup> See discussion of the case and Fuller's arguments below.

### 5.2.3 Abuse of monopoly system

While originally designed to encourage the setting up of new industries, the monopoly system began to be abused from the late 16<sup>th</sup> century onwards. Privy Council records show that between 1581 and 1603 patents were awarded regardless of whether a manufacture was new to the realm or not. For instance, many monopoly grants, such as for the production and sale of vinegar, starch and playing cards,<sup>58</sup> already existed in the realm at the time of the grant. At the same time, the Queen Elizabeth I rejected a large number of petitions for real inventions.

These practices negated the whole purpose of the issuance of letters patent - the introduction of new and useful manufactures. The abuse of monopolies contributed little to the development of the patent system. The consequences of the abuse were hindrance to trade and manufacture, high prices, inferior goods and all kinds of oppression.<sup>59</sup>

Abuse of monopoly system led to a judicial review of patents granted between 1581 and 1603. This review was sought by a London trader Thomas Allen in defending an infringement action brought against him by the holder of a playing card monopoly, Edward Darcy.

### 5.2.4 *Darcy v Allen (The Case of Monopolies)* (1602)

Before this case is examined further, it is important to note that, due to political sensitivities surrounding the first common law judicial review of a patent granted by the Crown, the judges on the Kings Bench did not issue reasons for the unanimous decision that Darcy's patent was void in this case. It was left to the case reporters, such as Coke,<sup>60</sup> Moore<sup>61</sup> and Noy<sup>62</sup> to announce to the world the unstated judicial reasons largely formed from submissions of counsel for Allen - Fuller and Dodderidge.<sup>63</sup>

---

<sup>58</sup> Hulme, above n 15, 53.

<sup>59</sup> Holdsworth, above n 9, 347.

<sup>60</sup> 11 Co Rep 84b-88b, 77 ER, 1260.

<sup>61</sup> (1602) Moore KB 671-675.

<sup>62</sup> (1603) Noy 173-185.

<sup>63</sup> Professor Davies made significant contribution to the author's understanding of the economic background and immediate consequences of the *Darcy v Allen* (or *The Case of Monopolies*, as it is better known under the name given to it by Coke): See D Seaborne Davies, 'Further Light on the Case of Monopolies' (1932) 48 *Law Quarterly Review* 394. Professor John H. Baker and Jacob I. Corre also supplemented the knowledge about the case by making analyses of some of the unpublished notes on the case. For instance, Baker examined several survived manuscript reports of *The Case of Monopolies*. One in a series of reports Baker called 'a uniformly minute and detailed account' of all the significant proceedings presented in the King's Bench from Michaelmas term 1598 through Hilary term 1604: See John H. Baker, 'The Dark Age of English Legal

#### **5.2.4.1 An infringement action against Thomas Allen**

It appears that in 1576, the Queen granted the sole right of importing, manufacturing and selling playing cards to Ralf Bowes and Thomas Bedingfield. The patent was re-issued twice before it was again re-issued in 1598 to Lord Darcy, a Groom of the Elizabeth's Privy Chamber, in consideration of his long and acceptable services to the Crown.<sup>64</sup> The term of his privilege was to extend to 21 years from the expiration of the former grant to Bowes.<sup>65</sup>

Since at the time of the grant the card industry was already established, the card monopoly was strongly resisted throughout the realm. Thus, notwithstanding the monopoly grant, there were many traders who were engaged in card manufacturing and selling activity. To prevent this activity, Bowes successfully sued infringers of his grant on several occasions.<sup>66</sup>

When Darcy received his patent in 1598, he was soon involved in patent infringement suits similar to those of Bowes'. In 1602, Darcy brought an infringement action against a London trader Thomas Allen. Allen denied most of the allegations, but admitted that he had sold a small quantity of playing cards and pleaded a right to do so, since he was a free citizen of London. The case was argued at great length in Trinity and Michaelmas terms in 1602. The King's Bench rendered judgment for Allen in Easter term in 1603.

#### **5.2.4.2 Argument for the plaintiff, Edward Darcy - a novel theory on which to base exception**

Altham's speech on behalf of Darcy opened the arguments in Trinity term in 1602. Tanfield completed Altham's argument. Attorney General Coke and the Solicitor General Flemming argued for Darcy in Easter term in 1603.

To defend the grant in *Darcy v Allen* meant constructing a novel theory on which to ground monopolies. Darcy's counsel did not deny the principle that a patent grant may wrongfully restrict the inheritance, liberty or freely exercised trade of the

---

History, 1500-1700' in *Legal History Studies* (1975) 1 (The Dark Age), reprinted in John H. Baker, *The Legal Profession and the Common Law* (1986) 135. Also Baker reviewed Coke's own unprinted notes on the case, which Baker announced and introduced to the world: See John H. Baker, 'Coke's Notebooks and the Sources of His Reports' (1972) 30 *Cambridge Law Journal* 59, 60 (Coke's Notebooks), reprinted in John H. Baker, *The Legal Profession and the Common Law*, (1986) 135, 177, 178.

<sup>64</sup> Davies, above n 63,399.

<sup>65</sup> Ibid.

<sup>66</sup> Ibid,400.

subjects, and therefore such grants must be excluded. The strategy was to show that the cards monopoly grant fell outside the principle, and thus should be excused from exclusion.

The foundation of that novel theory was the proposition that a gap existed between *lawful conduct* and *conduct that the law categorically prohibited and punished*. According to Darcy's counsel, the Crown was free to regulate conduct that fell in that gap. In his opening argument for Darcy, Altham argued that there was a class of activity, such as jousting and dice playing which 'although the law tolerates it and does not inflict punishment on those who do it, still it is unlawful'.<sup>67</sup>

Darcy's counsel applied this distinction not to the activity of making and selling cards, but to the *activity of card playing*. It was argued that because card playing was unlawful, the Queen was permitted to forbid it entirely. The argument involved showing card playing as a thing of 'vanity'. This meant that cards were not useful or necessary products. According to the argument, card playing could be considered a harmful practice that caused 'loss of time and decrease in the substance of many, the loss of the service and work of servants, causes of want which is the mother of woe and destruction'.<sup>68</sup>

Darcy's counsel raised the policy argument that since playing cards were the product of an unnecessary trade and promoted a wasteful and abused habit, the Queen could do what she saw fit with the whole business, and that, though the practice of card playing was not expressly prohibited and punished by law, its nature and the abuse involved with it made it 'unlawful'.<sup>69</sup>

It follows that what Darcy's counsel were arguing, in effect, was that card making, which was necessary prerequisite to card playing, was a dangerous and harmful activity, and that the Queen had authority to regulate and restrict this nature of the activity through a monopoly grant, which was supposed to serve the public interest. The novel theory was based on the proposition that notwithstanding its unlawful nature, as soon as the grant was regulated by the crown (by placing the power to control the amount of cards sold into the hands of a trusted servant), it was good and valid.

---

<sup>67</sup> Jacob I. Corre, 'The Argument, Decision and Reports of *Darcy v. Allen*' (1996) 45 *Emory Law Journal* 1261, 1298, citing the unprinted notes on the case, which Baker announced and introduced to the world: See Baker, 'Coke's Notebooks' above n 63.

<sup>68</sup> 11 Co Rep 85b.

<sup>69</sup> 11 Co Rep 85v-86, 77 ER, 1261-63.



In proposing that the activity was 'unlawful', and therefore of such nature that the Queen should regulate it, Darcy's counsel used the term 'inconvenience' along with 'unlawfulness'. For instance, in concluding Altham's argument for Darcy,<sup>70</sup> Tanfield noted that Darcy's grant was a tool of controlling the degree of card playing by placing the power to control the amount of cards sold into the hands of a trusted servant.<sup>71</sup>

Similarly, Solicitor-General Flemming, who represented Darcy in Easter term in 1603, argued that since the card playing was a harmful practice, the Queen was permitted to allow or forbid it entirely, as something *inconvenient* to the Commonwealth.<sup>72</sup>

It follows that inconvenience to the Commonwealth had the same meaning as unlawfulness: if an activity was dangerous and harmful, or involved an unnecessary trade that promoted a wasteful and abused habit, *the activity was inconvenient to the Commonwealth due to its unlawful nature*. Accordingly, the novel theory of Darcy's counsel was that playing cards were patentable because they were inconvenient.

#### 5.2.4.3 Argument for the defendant, Thomas Allen

Though the validity of Darcy's grant was the key question in *Darcy v Allen*, it was never Allen's counsel's intention to base the entire defence on the hope that the King's Bench would declare the patent void. Each of Allen's counsel, except Fuller, made arguments that Darcy did not have an action on the case.<sup>73</sup> According to Baker, the case was not presented to the King's Bench as one that revolved entirely around fundamental questions about the scope of royal prerogative. In some respects, it was an ordinary commercial dispute.<sup>74</sup>

---

<sup>70</sup> Altham opened the arguments for Darcy in Trinity term in 1602.

<sup>71</sup> The original text of this argument is the following: 'le roine poet aver prohibitte ousterment le use de ceo game . . . est loffice et dutie de roigne par restraine ceux illoiall games quex tendont al increase de vice et de plusors **inconveniences** in le realme et ceo le roine ad notablement performe in le fesans de cest graunt car el ad.' (Emphasis added)

<sup>72</sup> The original text of this argument is the following: 'Donques est apparant que le vice de carde playenge est mult **inconvenient pur le common weale** et par ceo besoigne reformation mes ad est dit coment carde playenge soet illoyal uncore le fesans de eux nest issint et de faire et vend cardes est un loyall trade.' (Emphasis added)

<sup>73</sup> For instance, Croke, on Allen's behalf, stated that he did not want to discuss the validity of Darcy's grant because he did not have time to consider it. Croke based his argument on showing that Darcy did not have the case of action even on the assumption that the grant was good: Corre, above n 67, 1269-1297.

<sup>74</sup> See Baker, 'Coke's Notebooks' above n 63, 177, 178.

### (a) Arguments of Fuller regarding restraint of trade

This issue is directly relevant to the question as to whether the fact that a patent restricts someone from unauthorised use of an invention makes that *patent void on basis of inconvenience*. It has already been noted on many occasions that the main argument against patenting of methods of medical treatment is based on the proposition that such patents might restrict physicians from practising their medical practice, thus should be disallowed on basis of inconvenience.<sup>75</sup> Hence, it is important to ascertain whether 'inconvenience' was ever used in this context by Fuller or any other counsel.

Fuller's most radical argument was that letters patents that purported to restrain subjects from engaging in a lawful trade were in contravention of several statutes, and so void.<sup>76</sup> However, given that the statutes were phrased in terms that arguably applied *only to lawful trades*, this argument would have been of no use against Darcy's primary argument that the trade was unlawful because the activity it made possible was unlawful (thus, Darcy argued, the Queen could regulate it).<sup>77</sup>

Yet, the statutes assisted Fuller's argument in that they reflected a policy against restraining subjects from practising a trade. However, this policy did not limit the Crown's power to issue patents. Fuller acknowledged that the limitation of the Crown's power was based on the requirement of the patent of invention.<sup>78</sup> In other words, the Crown clearly had the power to grant monopoly privileges to anyone who introduced a new invention into the realm, notwithstanding that the grant restrained subjects from practising a trade.

It must be noted that the review of the *Case of Monopolies*' report<sup>79</sup> and other relevant materials, in particular works of Davies<sup>80</sup>, Baker<sup>81</sup> and Corre<sup>82</sup>, has revealed that 'inconvenience' was never used to support the arguments for invalidity of patents on basis of restraint of trade.

---

<sup>75</sup> See discussions in Chapters 1-4.

<sup>76</sup> 11 Co Rep 88, 77 ER, 1265-66. The statutes were 9 Edw. 3, ch.1; 25 Edw. 3 (Stat. 3), ch. 2; and 27 Edw. 3, ch. 11. Coke also claimed that the grant contravened Chapter 18 of the Magna Carta.

<sup>77</sup> 11 Co Rep 88, 77 ER, 1265-66.

<sup>78</sup> Noy 183, 74 ER, 1139.

<sup>79</sup> (1603) Noy 173-185, 74 ER, 1131, 11 Co Rep 84b-88b, 77 ER, 1260.

<sup>80</sup> Davies, above n 63, 395.

<sup>81</sup> Baker, 'The Dark Age' above n 63; Baker, 'Coke's Notebooks' above n 63.

<sup>82</sup> Corre, above n 67.

**(b) Arguments of Fuller and Diott regarding patents of invention: 'inconvenient' meant 'no innovation'**

This argument was different from the one introduced by Darcy's counsel. It related to a *different kind of exception to invalidity of monopolies: that patents could only be granted for inventions.*

Both Diott and Fuller submitted that Darcy's grant was bad because he had not introduced any innovation into the craft of making playing cards.<sup>83</sup> Fuller relied on precedents to indicate that a patent of invention could be voided if it turned out that the grantee was not the true inventor.<sup>84</sup>

Fuller referred to *Matthey's* case in arguing that Darcy's patent should be void on the basis that card playing was contrary to law.<sup>85</sup> As discussed above, the issue whether a patent should be void for 'inconvenience' for being granted for improvements in an existing trade was central in *Matthey's* case. Though Fuller did not use term 'inconvenience', it could be inferred that Fuller, like Darcy's counsel, treated the term 'inconvenience' in the context of 'unlawfulness' or 'contrary to law'. Here is what Fuller said as to when a monopoly could be justifiable:

...where any man by his own charge and industry, or by his own wit or intention doth bring *any new trade* into the realm, or any engine tending to the furtherance of a trade *that never was used before*: and that for the good of the realm: that in such cases *the King may grant to him a monopoly* consideration of the good that he doth bring *by his invention* to the commonwealth: otherwise not.<sup>86</sup>

As discussed above, Darcy sought to justify the grant as a legitimate exercise of royal authority in the area of regulating harmful (unlawful) conduct. However, since *invention* was a necessary condition for a valid grant of monopoly, neither Diott nor Fuller had difficulties in establishing that the grant was never justified as a patent of

---

<sup>83</sup> Noy 183, 74 ER, 1139.

<sup>84</sup> In fact Fuller cited one of the earliest instances of patent's infringement litigation for which extensive records survive - the *Hastings case* of 1577 (no citations was found). In that case, John Hastings had been granted a 21-year patent for the exclusive manufacture, sale, and importation of a style of fabric called Harlan Freseadoes: PRO C 66/1054, m. 14 (1569). Hastings sued a group of clothiers on the equity side of the Exchequer, and claimed that the clothiers were infringing his grant. The clothiers produced evidence that their cloth differed from Hastings' and that their cloth had been manufactured in England before Hastings' patent had been granted. Fuller concluded that the defendants were discharged because the bays were made before in the realm: Noy 173, 183.

<sup>85</sup> Noy 173, 183.

<sup>86</sup> *Darcy v Allen* (1602) Noy 173, 183 (*Emphasis added*).

invention, and thus had to be void on basis of being contrary to law or inconvenient.

#### **5.2.4.4 Conclusion regarding *The Case of Monopolies***

In the absence of a judicial opinion, the exact scope of *Darcy v Allen* remains unclear, like *Matthey's* and *Bircot's* cases discussed above.<sup>87</sup> This makes it difficult to establish the precise reasons for the decision in this 400 year old case. All that is left is a report of the plaintiff's counsel, prepared some 15 years later.

Notwithstanding the above, the reports of the arguments of counsel do reveal the development of legal analysis regarding granting of the monopoly patents. The *Case of Monopolies* has been regarded as one of the outstanding decisions of the English Common Law.<sup>88</sup> It is possible to draw the following inferences from the evidence presented:

- From the arguments of Allen's counsel it follows that 'inconvenience' was used to establish unlawful conduct and had the same meaning as 'unlawfulness'. If an activity was dangerous and harmful, or involved an unnecessary trade that promoted a wasteful and abused habit, the activity was inconvenient to the Commonwealth due to its unlawful nature.
- From the fact that Fuller referred to *Matthey's* case, in arguing that Darcy's patent should be void for being contrary to law, it could be inferred that Fuller also treated the term 'inconvenience' in the context of 'unlawfulness' or 'contrary to law'.
- 'Inconvenience' was never used to support the arguments for invalidity of patents on basis of restraint of trade.
- The monopoly at issue was found to be contrary to the common law of the land, statute law and liberty of the subject because it was given to a well-known commodity, which was not an invention, and not because it inconveniently restrained someone from practising a trade.

---

<sup>87</sup> For instance, Jacob I. Corre argues that the case summaries produced by many historians who rely heavily on the report published by Coke in 1615, probably exaggerated the extent to which the case laid the limitations on the royal prerogative. According to Corre, what Coke published in his report fifteen years later as the reasons of the court was probably based on his version of an informal private communication to him by one of the Justices and 'was heavily filtered through the lenses of his own ideological project of the time': see Corre, above n 67, 1269-1271.

<sup>88</sup> See Davies, above n 63, 395. According to Davies, the case 'deserves to be placed in the most select list of celebrated common law decisions.'

- The reports provide specific criteria directly relevant to the question of when monopolies will be treated to be contrary to the law or mischievous to the state, or hurt of trade in the sense of raising prices. According to the case, there were three specific criteria for invalidation of monopolies:
  1. the prices of the commodity had to have risen;
  2. the quality of the product needed to have declined; and
  3. artisans must have lost work as a result of the monopoly.<sup>89</sup>

These criteria were later reworded and reappeared in the King's ninth proviso of the Book of Bounty.

### 5.2.5 The Book of Bounty (1610) - the King's ninth proviso

In 1603 James I acceded the English throne. Notwithstanding the outcome in *Darcy v Allen*, he continued to grant, as Coke commented, 'odious' monopolies.<sup>90</sup> However, following political pressure arising from granting those royal prerogatives, in 1603 the King issued a proclamation against monopolies. In 1610 the proclamation, widely known as 'The Book of Bounty', was published wherein James I declared that monopolies were against the laws of the realm and expressly commanded that 'no suitor presume to move Us' to grant them.<sup>91</sup> Monopolies for *new* inventions were, however, excluded from this prohibition, provided they were 'not contrary to law or hurtful to the state and trade, or generally inconvenient'<sup>92</sup> (so called as *the King's ninth proviso*).

Taking into account the similarity in the wording of the report of the submissions of the counsel for Allen (Fuller) in *Darcy v Allen*, the fact that Coke was the Attorney-General before the King's Bench in that case, and that he was the opponent of the unfettered exercise of the Royal prerogative, it could be suggested that the wording of the King's ninth proviso had been drawn by Coke from Fuller's submissions and introduced to the King as the draft for the ninth proviso to the Book of Bounty. This exact wording in the Book of Bounty later reappeared as the proviso to s 6 in the *Statute of Monopolies*.

<sup>89</sup> Noy, 173; 11 Co Rep 84b; Moore KB 671; Harold G. Fox, *Monopolies and Patents: A Study of the History and Future of the Patent Monopoly* (1947), 87-9, 318-26; Price, above n 37, 34; Davies, above n 16, 103.

<sup>90</sup> 77 English Reports, 1264, 1266.

<sup>91</sup> Guy Aldous, *Terrell on the Law of Patents* (11<sup>th</sup> ed, 1965), para 3.

<sup>92</sup> *Ibid.*

## 5.3 THE ENACTMENT OF THE STATUTE OF MONOPOLIES (1621-1624)

### 5.3.1 Debating the Bill

In 1619 matters came to a crisis point as a result of increasing scandalous abuses of the monopoly system. One such example was the imprisonment of five silk mercers by a patentee. Although James I released them, he proclaimed a support for the continuance of the monopoly system.<sup>93</sup> The following year there was debate in Parliament over a patent for inns, and by 1621, public anger and complaints about monopolies were widespread.<sup>94</sup> When Parliament assembled in 1621 patents were one of the first issues debated, and the Commons decided to introduce a Bill to give a statutory power to declare monopolies illegal.<sup>95</sup>

It appears that Coke played a significant role in drafting the Monopolies Bill. Taking the crisis surrounding monopolies as a political opportunity, Coke introduced the original draft (the precursor to the *Statute of Monopolies*) into Parliament and acknowledged that he drafted the Bill so that it was 'grounded upon the King's own Book'.<sup>96</sup> Coke also was a member of the committee to consider the Bill.<sup>97</sup>

Even though the various sections of the Monopolies Bill had been substantially debated in the House of Commons and the Upper House and altered many times (by Coke and others),<sup>98</sup> the wording of the proviso to s 6 had been left substantially untouched and again, appeared as it had been drawn from the submissions of the counsel for Allen in *Darcy v Allen*.

### 5.3.2 19 April 1624 conference in the House of Commons - the provisos to the Monopolies Bill

During the debating of the Monopolies Bill, it was decided that the Bill should have a 'main body' and provisos.<sup>99</sup> According to Coke's report of the 19 April 1624 conference to the Commons, the Lords introduced 17 exceptions to the Bill.

---

<sup>93</sup> Thompson, *Magna Carta – Its Role in the Making of the English Constitution – 1300-1629* (1943), 301.

<sup>94</sup> Klitzke, above n 5.

<sup>95</sup> Chris R Kyle, 'But a New Button to an Old Coat: The Enactment of the Statute of Monopolies, 21 James I cap.3' in Frank Cass, *Legal History* (1998) vol 19, N3, 202-223.

<sup>96</sup> Kyle, above n 95, 223.

<sup>97</sup> The committee was comprised of Coke, William Noy, Crew, William Denny, Francis Glanville and Walter: see Kyle, above n 95, 202-223.

<sup>98</sup> Kyle, above n 95, 202-223.

<sup>99</sup> Ibid.

At the conference, Viscount Mandeville argued that there was a contradiction between the main part of the Bill, which declared all monopolies void, and the specific saving clauses. Coke, however, explained that those clauses were *provisos*, not saving clauses.<sup>100</sup> He explained that the provisos only affected the declaratory law to the extent that they were exempted from the penalties imposed by the Bill.<sup>101</sup>

### 5.3.2.1 New inventions are not void - further light on the meaning of 'inconvenient'

The Lords were concerned about the status of new inventions. The Monopolies Bill did not declare the future new inventions void and it noted that *these 'should not be inconvenient'*.<sup>102</sup> Mandeville argued that additions to old inventions might or might not be inconvenient, depending on the case.<sup>103</sup> Coke agreed on the point regarding new inventions and stated that the Bill should clarify that these should not be inconvenient (though it was never clarified, taking into account the proviso's ambiguous meaning). However, Coke did not accept that additions to old inventions should be classified as a new invention 'but a new button to an old coat'.<sup>104</sup>

The above is a clear illustration of the main argument presented in this Chapter: only patents that are given to a known commodity should be void on basis of being inconvenient or contrary to law. Monopolies to new inventions *should not be declared invalid on the basis of inconvenience*.

### 5.3.3 No distinction between 'contrary to law' and 'inconvenient'

In support of earlier argument in this Chapter, it is necessary to refer to work of Elizabeth Read Foster,<sup>105</sup> who states that when patents were reviewed in Parliament during 1621 and 1624, an obscure distinction between 'contrary to law' and 'inconvenient' was employed. A 'contrary to law' patent was one contrary to a

---

<sup>100</sup> It must be noted that the term *proviso* is used here to describe the whole s 6 (which the author referred to earlier as the 'main provision'). Within Section 6 there is another proviso (the proviso to s 6). This is the general inconvenience proviso.

<sup>101</sup> Kyle, above n 95, 213.

<sup>102</sup> Kyle, above n 95, 202-223, 287; S Rawson Gardiner, *Notes of Debates in the House of Lords ... 1624 and 1626* (1879) Vol LXXXI, 50.

<sup>103</sup> Kyle, above n 95, 202-223.

<sup>104</sup> Kyle, above n 95, 287; Gardiner, above n 102.

<sup>105</sup> Kyle, above n 95, 203, 214.

<sup>105</sup> Elizabeth Read Foster, 'The Procedure of the House of Commons against Patents and Monopolies 1621-1624' in Stuart England (ed), *Essays in Honour of Wallace Notestein* (1960), 74-75.

*strict legal requirement for a valid patent* (for example, lack of new invention or not the first inventor) and thus infringed the rights of the subjects. An 'inconvenient' patent was one clearly obnoxious and injurious to the best interest of the Commonwealth, due to its lack of invention, which was the consequence of breach of a legal requirement for a patent. According to Foster, 'both were grounds for attacking patents and the *theoretical analytical distinction was rarely strictly maintained* in actual debates.'<sup>106</sup>

Moreover, though Coke never commented on the meaning of the term 'generally inconvenient', an argument based on inconvenience, he said, was of great weight in law ('*argumentum ab inconvenienti plurimum valet in lege*').<sup>107</sup> After stating this maxim, Coke added the following: not only what is lawful but also what is convenient is to be considered. Nothing that causes inconvenience can be taken as lawful ('*Non solum quod licet sed quod est conveniens est considerandum. Nihil quod est inconveniens est licitum*').<sup>108</sup>

From the above comments on the meaning of inconvenience, it is concluded that inconvenience and unlawfulness employed similar considerations and interpretative factors.

#### 5.3.4 The royal assent

Debate in Parliament continued, and in May 1624 the Monopolies Bill was reported by the Lord President of the Upper House as 'fit to pass, with some Amendments and Provisos'.<sup>109</sup> On 25 May 1624 Coke reported that the committee agreed to the amendments and provisos. On 29 May the King gave the royal assent to 73 Bills, including the Monopolies Bill (James I. cap. 3), 'An Act concerning Monopolies and Dispensations with the penal Lawes and the Foreytur thereof', so called the *Statute of Monopolies*.

Thus, the *Statute of Monopolies* declared all monopolies, dispensations and grants to compound penalties void, aside from the exception contained in s 6. This section defined the privileges the Crown might grant to new inventors. All such grants were

---

<sup>106</sup> Ibid.

<sup>107</sup> Co Litt 66a, cited by Bowen LJ in *Gard v London sewers Comrs* (1885) 28 Ch D 486, 511.

<sup>108</sup> Co Litt 178, cited by F Bennion, *Statutory Interpretation, A Code* (2<sup>nd</sup> ed, 1992), 686.

<sup>109</sup> Kyle, above n 95, 203, 215.



to be tried at common law. Section 6 correlated with the King's ninth proviso,<sup>110</sup> and only added the limitation of monopoly term of 14 years.

#### 5.4 POST - 1624 HISTORY OF THE PROVISO

Since the Restoration,<sup>111</sup> patents declined in importance. According to Harold G. Fox, there is only one reported case between the enactment of the *Statute of Monopolies* and the end of the seventeenth century, and only one more case reported until 1765.<sup>112</sup> Notwithstanding this fact, the fundamental framework in either granting/revoking patents or legal doctrines remained that of the early common law.<sup>113</sup> The main patent law concept and the traditional discretionary policy - based process discussed above did not change.

According to MacLeod, during the late seventeenth century, patents were often granted with little investigation.<sup>114</sup> This approach dominated only as long as no interested party initiated objection to a particular patent grant. When an objection did occur, it usually prompted the Privy Council to demand more information and conduct a more thorough investigation, especially if it was alleged that the patent was 'contrary to law' or 'inconvenient'.<sup>115</sup> For instance, in 1663 Lord Treasurer, Southampton supported his recommendation of Garil's patent by saying that 'in case any unseen abuse be found out' it could be revoked by the Privy Council.<sup>116</sup> It must be noted here again that MacLeod does not make any distinction between 'contrary to law' or 'inconvenient'. MacLeod states that when patents were subjected to review in the Privy Council, the process was much closer to the traditional discretionary policy based process discussed above.

Moreover, until the nineteenth century, there was no change in patent law that affected the English concept of patents - the discretionary privilege concept was still followed by Privy Council when it was raised by interested parties in relation to patent grant.<sup>117</sup> As late as 1847, in one of the earliest patent law treatises W.M.

---

<sup>110</sup> It must be noted that the term *proviso* is used here to describe the whole s 6 (which the author referred to earlier as the 'main provision'). Within Section 6 there is another proviso (the proviso to s 6). This is the general inconvenience proviso.

<sup>111</sup> See above n 32.

<sup>112</sup> Fox, above n 89. See also: Christine MacLeod, *Inventing the Industrial Revolution: The English Patent System 1660-1800* (1988), 61-62; EW Hulme 'On the Consideration of the Patent Grant Past and Present' (1897) 13 *Law Quarterly Review* 313, 318.

<sup>113</sup> MacLeod, above n 112, 20-39.

<sup>114</sup> *Ibid*, 42.

<sup>115</sup> *Ibid*, 45-47.

<sup>116</sup> *Ibid*, 47.

<sup>117</sup> *Ibid*, 45-47.

Hindmarch included a section regarding the Revocation of a Patent 'by the Queen or the Privy Council'.<sup>118</sup> Hindmarch described the revocation proceedings in terms that corresponded to the traditional privilege concept:

The grant of a patent is a matter of grace and favour and therefore... the Crown may annex any conditions it pleases to the grant... with the view of enabling the Crown to determine *any illegal grant* which may be unadvisedly made, without allowing the public to be put to the trouble or cost of resisting the unlawful patent.<sup>119</sup>

According to Hindmarch, by 1847, however, this was already 'a history' with little practical significance. He concluded:

[t]here is no instance in modern times of the determination of a patent under this proviso, but there can be no doubt that the power it confers could be exercised if a case should arise calling for such an extraordinary interference of the Crown for the protection of the public.<sup>120</sup>

There is no doubt that the traditional discretionary approach of the Privy Council would be applied notwithstanding the fact that it was falling out of favour in the broader context.

## 5.5 APPLICATION OF THE RULES OF STATUTORY INTERPRETATION

This analysis illustrates that early common law interpretation of term 'generally inconvenient' focused on inventiveness and novelty, but Chapter 4 showed that the modern interpretation, at its heart, is focused on restraint of trade, or restriction on use per se. Essentially, it is based on the argument that even though a method of medical treatment might be inventive, new and useful, it may nevertheless restrict medical practice, and thus should be void.

It is submitted that this modern interpretation has twisted the original meaning of the term 'inconvenient' for advancement of different policy reasons. In the modern context, the term has been used to promote 'public policy',<sup>121</sup> 'social policy',<sup>122</sup>

---

<sup>118</sup> W.A. Hindmarch, *Treatise Relating to the Law of Patent Privileges for the Sole Use of Inventions* (1847), 431.

<sup>119</sup> *Ibid.*

<sup>120</sup> *Ibid.*

<sup>121</sup> *Joos v Commissioner of Patents* (1972) 126 CLR 611, 623 (Barwick CJ).

<sup>122</sup> *Anaesthetic Supplies Pty Ltd v Rescare Ltd* (1994) 50 FCR 1, 45 (Wilcox J).

'ethics'<sup>123</sup> and 'morals'<sup>124</sup> in the context of the restraint of trade,<sup>125</sup> and not in the context of inventiveness or novelty.<sup>126</sup> In essence, the argument that has been used is that medical practitioners should not be restrained from practising their trade, based on these underlying social policy concerns. Whilst there may be some merit to such arguments, this thesis argues that general inconvenience is not the appropriate vehicle for driving them.

The aim in this section is to analyse the modern interpretation of the proviso to s 6 using the general principles of statutory interpretation.

### 5.5.1 The literal approach and the phrase 'such manufactures [shall] be not... generally inconvenient'

If it is possible to conclude that the term 'generally inconvenient' is clear and carries a plain meaning, then according to the literal approach to statutory interpretation, it should be construed according to the rules of grammar.<sup>127</sup> As Bennion puts it, 'the grammatical meaning of an enactment is its linguistic meaning taken in isolation.'<sup>128</sup> In some cases, however, the grammatical meaning might not correspond with the intention of the founders and may lead to doubts in law.<sup>129</sup>

The modern Oxford English Dictionary interprets the word 'generally' as to 'include every particular, as a whole, collectively; universally; with few or no exceptions; in general sense or way; opposed to 'specially''.<sup>130</sup> The word 'inconvenient' means: 'unsuitable, inappropriate; morally or ethically unsuitable; unfavourable to comfort; something inconsistent with reason; something morally unfitting.'<sup>131</sup> Putting this together, a grammarian would say that it looks like 'generally inconvenient' means something that is 'in general sense, as a whole, unsuitable or inappropriate or morally or ethically unsuitable or unfavourable to comfort'. Thus, following a literal interpretation the suggestion might be that the proviso was designed to advance arguments of morals, ethics and/or public policy.

<sup>123</sup> *Eli Lilly & Company's Application* [1975] RPC 438, 445; *Anaesthetic Supplies Pty Ltd v Rescare Ltd* (1994) 50 FCR 1, 45 (Wilcox J).

<sup>124</sup> *Bristol – Myers Squibb Co v F H Faulding & Co Ltd* [2000] FCA 316, 355 (Finkelstein J).

<sup>125</sup> *Ibid.*

<sup>126</sup> *Darcy v Allen* (1603) Noy 173-185, 74 ER 1131, 11 Co Rep 84b-88b, 77 ER 1260.

<sup>127</sup> P Langan, *Maxwell on the Interpretation of Statutes* (12<sup>th</sup> ed, 1969, reprinted 2003), 28 F Bennion, *Statutory Interpretation, A Code* (4<sup>th</sup> ed, 2002), 320.

<sup>128</sup> Bennion, above n 127, 321.

<sup>129</sup> PP Maxwell, *On the Interpretation of Statutes* (1875); Langan, above n 127, 29; DC Pearce and RS Geddes, *Statutory Interpretation in Australia* (6<sup>th</sup> ed, 2006), 23-24; Bennion, above n 127, 320-323.

<sup>130</sup> *The Oxford English Dictionary*, (Clarendon Press, Oxford, 1970) vol V, 105.

<sup>131</sup> *Ibid.*, 176.

The history presented above reveals that the term 'generally inconvenient' was indeed used to advance public policy purposes. However, the *nature* of those policy considerations was different from those implied by the dictionary meaning provided above, and also different from those advanced by modern courts. Though the application of these policy considerations might use similar weighing technique and arrive at a similar conclusion (invalidation of patents on public policy grounds), they are of a fundamentally different nature or based on a different concept.<sup>132</sup> The term 'generally inconvenient' was not meant to be reduced to a question of verbal interpretation, but to be interpreted as a qualification at the end of the general statement in s 6, in the context of s 6 as a whole, that is, invalidation of known monopolies that do not fulfill the 'manner of manufacture' requirement.

Hence, it would appear that there is a significant difference between the modern dictionary meanings of 'generally' and 'inconvenient' and the meaning of these words as used in 1624 in the *Statute of Monopolies*. On this basis, it is submitted that the meaning of the term 'generally inconvenient' is far from clear. The term carries more than one meaning and could be interpreted in many ways. The conclusion, therefore, is that the term is ambiguous. It is concluded that the term 'generally inconvenient' should not be interpreted literally for the following reasons:

- the term is not clear or unambiguous;
- the literal meaning of the term conflicts with the purpose or mischief that Parliament intended to deal with; and
- according to principles of statutory interpretation, the *proviso* should not to be taken 'absolutely in [its] strict sense',<sup>133</sup> in isolation to the rest of the whole provision and its context.

### **5.5.2 The purposive/ legislative intent approach and the phrase 'such manufactures [shall] be not... generally inconvenient'**

Lord Reid in *Kirkness (Inspector of Taxes) v Hudson*<sup>134</sup> explained that the inherent uncertainty of words is normally cured by the context, that is, by selection of other words in the sentence. To resolve uncertainty, the court should employ the purposive approach to look at the overall intention of the legislature as discovered from reading the statute or the words in the section as a whole. Once it is apparent

---

<sup>132</sup> See Part 5.6.3 of this Chapter.

<sup>133</sup> *R v Dibdin* [1910] P 57, 58.

<sup>134</sup> [1955] AC 696, 735.

that the term 'generally inconvenient' is uncertain or ambiguous, it is necessary to determine the purpose of the statute and adopt an interpretation of the meaning which is consistent with that purpose. The purpose is usually deduced by looking at the statute as a whole. Thus, taking into account the history of the proviso, the court must answer questions such as: what is the context of s 6 and its proviso? what does the *Statute of Monopolies*, and s 6 as a whole, provide for? what does the history of its enactment reveal?

The historical analysis of *Statute of Monopolies* shows that it was primarily a declaration of the common law of monopoly, and s 6 did nothing but continue the common law exclusion of patents for invention from the statutory prohibition of monopolies.<sup>135</sup> The *mischief or defect* was the abuse of monopoly system by granting monopolies to known commodities, and the *remedy* for this mischief was the pronouncing of all monopolies void, except those that were a manner of manufacture, novel, inventive, useful and not previously known or used in the realm. Following on from this conclusion, it is necessary to reject the modern dictionary definition of the term 'generally inconvenient' and refer to the defect in the common law the 1624 Parliament intended to cure. The term should not be interpreted in isolation from the rest of the section and its context.

### 5.5.3 The general rule of interpretation of provisos

When considering the context of the proviso to s 6 of the *Statute of Monopolies*, it is necessary to consider the style of drafting that was used at the time. Modern statutory drafting is quite different from the form of drafting adopted by draftsmen of the *Statute of Monopolies*. In modern drafting, the tendency is for two different propositions to be presented in separate sections or subsections. Consider, for example, a section of legislation that is split into subsections (1) and (2). Here subsection (2) might begin 'Subject to subsection (1)...', or 'Notwithstanding anything in subsection (1)...'. That is, subsection (1) provides the general proposition and subsection (2) provides the qualification.

Section 6 of the *Statute of Monopolies*, on the other hand, contains both a general statement, and an ancient verbal formula, called 'the proviso' that makes a proposition or qualification at the end of that general statement.<sup>136</sup> The effect of this style of drafting is that s 6 allows monopolies that are a manner of new manufacture (**main provision**), *but only in so far as* (the words 'so as also they be'

---

<sup>135</sup> S Ricketson, *The Law of Intellectual Property* (1984), 552.

<sup>136</sup> For early references to provisos in statutes see Hatsell, *Parliamentary Precedents* (1575) 3.46; (1660) 3,114.

suggest this) those manufactures are 'not contrary to the law or mischievous to the state, by raising prices of commodities at home, or hurt of trade, or generally inconvenient' (*proviso*).

According to the general rule of interpretation of provisos as laid down or adopted by the courts and supported by leading textbooks on statutory interpretation in England and Australia,<sup>137</sup> the words of a proviso are not to be taken 'absolutely in their strict sense';<sup>138</sup> a proviso is of necessity 'limited in its operation to the ambit of the section which it qualifies.'<sup>139</sup> As Langan observes, so far as the main section itself is concerned, the proviso again receives a restricted construction.<sup>140</sup> Where the section confers powers, 'it would be contrary to the ordinary operation of a proviso to give it an effect which would cut down those powers beyond what compliance with the proviso renders necessary.'<sup>141</sup> According to Bennion, in the case of a proviso, a statute must be construed as a whole.<sup>142</sup> He further explains that a section containing a proviso must also be construed as a whole, within that statute.<sup>143</sup>

As a consequence, the proviso to s 6 should be treated as a provision that is dependent on the main statement. Adopting the modern style of drafting, s 6 tends to state the following:

- (1) Provided also that any declaration before mentioned [*monopolies*] shall not extend to any letters patent and grants of privilege for the term of fourteen years or under, thereafter to be made, of the sole working or making of any manner of new manufactures within this Realm, to the true and first inventor and inventors of such manufactures which others at the time of making such letters patent and grants shall not use.
- (2) *Those monopolies that lack of any requirement provided in subsection (1) above shall be held contrary to the law or mischievous to*

<sup>137</sup> Maxwell, above n 129; Langan, above n 127, 189; Pearce and Geddes, above n 129, 124-125; Bennion, above n 127, 492-493.

<sup>138</sup> *R v Dibdin* [1910] P 57.

<sup>139</sup> *Lloyds & Scottish Finance Ltd v Modern Cars & Caravans (Kingston) Ltd* [1966] 1 QB 764, 780 (Davies J).

<sup>140</sup> Langan, above n 127, 190.

<sup>141</sup> In his explanation, Langan quotes from *Re Tabrisky, ex p. Board of Trade* [1947] Ch 565 (Lord Greene MR), 568.

<sup>142</sup> Bennion, above n 127, 494.

<sup>143</sup> Bennion, above n 127, 494, citing *Jennings v Kelly* [1940] AC 206, 229.

the state, by raising prices of commodities at home, or hurt of trade, or generally inconvenient.

#### 5.5.4 The modern usage of the phrase 'such manufactures [shall] be not... generally inconvenient'

The decision in *Joos v Commissioner of Patents*<sup>144</sup> (**Joos**) was the first decision where an Australian judge mentioned the proviso to s 6. As noted in Chapter 4, prior to *Joos* the exclusion of medical treatments from patenting was based on the principle that they were not 'in some way associated with commerce and trade'.<sup>145</sup> As the history revealed, the proviso had never been applied by the courts in relation to any patentable subject matter after 1765.<sup>146</sup> When, however, Barwick CJ made it clear that methods of medical treatment do have a commercial application, he justified the exclusion on public policy grounds. Without considering either the meaning or the original reason for the proviso, the Chief Justice found that a public policy ground could be read into the term 'generally inconvenient' located in the proviso. Thus, the Chief Justice pronounced the following:

If I had to do so, as at present advised, I would place the exception, if it is to be maintained, *on public policy* as being, in the language of the *Statute of Monopolies*, 'generally inconvenient'...<sup>147</sup>

Similarly, as discussed in Chapter 1, when the longstanding practice<sup>148</sup> of exclusion of methods of medical treatment from patenting in the UK was removed by the decision of the Australian High Court in *NRDC*, the UK courts started searching for some other ground on which to base the exclusion. In *Eli Lilly & Company's Application*<sup>149</sup> (**Eli Lilly**), the Patents Appeal Tribunal<sup>150</sup> clearly stated that the restriction still applied regardless of other changes in law and refused a patent application, for the first time, on the basis of the proviso to s 6 of the *Statute of Monopolies*.

Although the Australian Federal courts in *Anaesthetic Supplies Pty Ltd v Rescare Ltd*<sup>151</sup> (**Rescare**) and *Bristol-Myers Squibb Co v F H Faulding & Co Ltd*<sup>152</sup> (**BMS**)

<sup>144</sup> (1972) 126 CLR 611.

<sup>145</sup> *In the Matter of C & W's Application for a Patens* (1914) 31 RPC 337.

<sup>146</sup> Fox, above n 89, 119; See also: MacLeod, above n 112, 61-62; Hulme above n 112, 318.

<sup>147</sup> *Joos v Commissioner of Patents* (1972) 126 CLR 611, 623 (Emphasis added).

<sup>148</sup> *In the Matter of C & W's Application for a Patent* (1914) 31 RPC 235.

<sup>149</sup> [1975] RPC 438.

<sup>150</sup> Per Graham and Whitford JJ.

<sup>151</sup> (1994) 50 FCR 1.

<sup>152</sup> [2000] FCA 316.

decided in favour of patenting of methods of medical treatment, the in each case courts undertook a public policy 'balancing exercise' in light of the proviso to s 6 in order to find a justification for either granting or excluding patent protection for processes of medical treatment. For instance, Lockhart J in *Rescare* decided that there would be less incentive to expend time, effort and money to make discoveries of new medical uses for known chemicals if no financial return (by means of patents) was to be available.<sup>153</sup> Sheppard J, on the other hand, strongly dissented in *Rescare* on the point that to grant a patent to the methods of medical treatment would be 'generally inconvenient' within the public policy proviso to s 6. His Honour argued that though a surgical procedure invention might be 'greatly beneficial to mankind',<sup>154</sup> granting a monopoly over such procedure might mean the 'death or unnecessary suffering of countless people'.<sup>155</sup>

In deciding whether patenting of methods of medical treatment was 'generally inconvenient', Black CJ and Lehane J in *BMS* acknowledged that, at first sight, it was easy to see how it could be argued that it was 'generally inconvenient' to grant a patent to a novel life-saving therapeutic method. They stated that it would be based on a belief that such a method must be available universally and without restriction. However, their Honours concentrated on logic, rather than ethics.<sup>156</sup>

*At no stage* did judges consider the meaning of the language of the *Statute of Monopolies*, nor did they look at history of s 6 in order to find out the intention of the Parliament in placing the proviso. Neither could it be said that the judges read the proviso with the rest of s 6, nor questioned the reason for the proviso and its meaning. Though in *BMS* Finkelstein J made a brief inquiry into the history of patent law and s 6 of the *Statute of Monopolies*, his Honour did not consider the meaning and thus effect of its proviso.

With respect, every judge in the above mentioned cases simply saw 'generally inconvenient' as a term that should be interpreted in *isolation* from the rest of s 6, to which it is a proviso. They also interpreted the term in such a way as to give them the opportunity to make moral judgments in relation to restraint of trade. However, they provided no justification for so doing. As the consequence, the term was interpreted as a separate public policy requirement for patentability, capable of being used as a sole ground for denial a patent protection. While it could perhaps be argued that, in reliance on the literal approach to statutory interpretation, the

---

<sup>153</sup> *Anaesthetic Supplies Pty Ltd v Rescare Ltd* (1994) 50 FCR 1, 18.

<sup>154</sup> *Ibid*, 41.

<sup>155</sup> *Ibid*.

<sup>156</sup> *Bristol-Myers Squibb Co v F H Faulding & Co Ltd* [2000] FCA 316, para 17.



dictionary meaning of 'generally inconvenient' may provide an avenue for the courts to introduce public policy considerations, the inherent ambiguity of the phrase suggests that this is not the most appropriate approach to take. The purposive approach, on the other hand, favours an inquiry into the intention behind the provision. It is argued that the judges in these modern cases should have considered the legislative history of the provision and that, had they done so, they would have reached a different conclusion. It is submitted that the founders did not intend that the proviso and the term 'generally inconvenient' be given this public policy role.

## **5.6 CONCLUSION**

### **5.6.1 The *Statute of Monopolies* captured limitations already assigned by the common law**

The analysis of the early history of patent law in this Chapter indicates that prior to the introduction of the *Statute of Monopolies*, the common law already provided an adequate remedy against monopolies and, though legislation subsequently became necessary, there was no deficiency in law in this area - the common law was just 'neglected, evaded, and defied'.<sup>157</sup>

As illustrated above, the basis for the submissions of the counsel for Allen in *Darcy v Allen* reflected the common law position regarding granting 'odious' monopolies. These submissions were used as the main source for the King's ninth proviso in the Book of Bounty, and then for the first draft of the proviso to s 6 of the *Statute of Monopolies*. It is submitted that neither *Darcy v Allen* nor the Book of Bounty established a new law. Neither did the *Statute of Monopolies*. These only reasserted the common law in this area - the monopoly could only be granted to a new trade, which was useful - granting a monopoly otherwise would be harmful to the realm, thus cause inconvenience.

### **5.6.2 Sources for the term 'inconvenient'/'inconveniency'**

This historical analysis also illustrates that the limitation of time and apprenticeship clauses were the two sources for the term 'inconvenience'. When these clauses

---

<sup>157</sup> Price, above n 37. Similarly, Hulme states that 'in other respects...the statute must be interpreted as recapitulating limitations already assigned by the common law, which limitations in their turn... are such as were commonly prescribed in these grants for the purpose of safeguarding the powers with which the grantee was thus invested', see: Hulme, above n 15, 55.

were breached the monopoly was considered to be inconvenient to the realm. It is submitted that the proviso to s 6 was simply a reproduction of these clauses.

Moreover, the term 'inconveniency' covered issues like novelty and priority of invention. *Matthey's* and *Bircot's* cases and *Darcy v Allen*, as well as reports of the Parliament debates during 1621 and 1624, support the proposition that when the subject of the monopoly was not new - the monopoly was considered to be inconvenient to the realm. These also highlight that the 'inconvenience' was used in the same context as 'contrary to law', 'mischievous to the state' and 'hurt of trade'. It is concluded that these terms had no distinction in their meaning. The author agrees with Davies who assumes that the abuses specified in the proviso to s 6 - 'so as also they be not contrary to the law or mischievous to the state, by raising prices of commodities at home, or hurt of trade, or generally inconvenient' - are all covered by the term 'inconveniency'.<sup>158</sup>

### 5.6.3 Is the term 'a catch-all justification' or a specific saving clause?

From the first reference, it seems that the term 'generally inconvenient' in s 6 was meant to capture every deficiency in a monopoly grant so it could be viewed as 'a catch-all justification' for invalidity of the grant or the specific saving clause. It could therefore be concluded that by using the inconveniency proviso as a discretionary-based policy instrument, modern courts follow the originally intended meaning of the term. However, the explanation given by Coke during the debate of the Monopolies Bill regarding the inclusion of s 6 as a *proviso* does not support this, and nor do the general rules of interpretation of provisos laid down or adopted by the courts.<sup>159</sup> As a result, and with guidance from the reasoning of Kyle<sup>160</sup> it is concluded that the provisos, either s 6 itself or the general inconvenience proviso within s 6, were *clauses that declared the law* as it was, and not saving clauses.

Moreover, notwithstanding the term was used to advance public policy considerations in the ancient case law and debates, the discussion above shows that basis for those policy considerations was quite different from those advanced by modern courts. The early common law cases indicate that the discretion was exercised in the name of the 'public good' to prevent *unlawful* inventions. According to the *Darcy v Allen*, those patents that lacked invention and novelty were contrary to the public good or unlawful, thus were considered to be inconvenient to the Commonwealth due to their unlawfulness. It follows, therefore,

---

<sup>158</sup> Davies, above n 16.

<sup>159</sup> See discussion regarding interpretation of provisos in Part 5.5.3 of this Chapter.

<sup>160</sup> Kyle, above n 95, 213.

that the royal discretion was based on satisfaction of legal requirements for a valid patent - requirements of invention and novelty. The decisions in *Matthey's* and *Bircot's* cases lend further support to the above proposition.

#### 5.6.4 How should the term be interpreted?

The discussion in this Chapter aimed to show that the proviso to s 6 should be interpreted, as Sir Edward Coke stated, according to the intent of the Parliament that enacted it,<sup>161</sup> because the sole object in statutory interpretation is to arrive at the legislative intention.<sup>162</sup> As Lord Goddard CJ stated, a court cannot add words to a statute or read words into it that are not there.<sup>163</sup> If the Parliament made an unclear statement, it should amend the statute. Unless and until it is done, the words 'are frozen in their imperfect state'<sup>164</sup> and the court is bound to endeavour to place some meaning upon them. In so doing it gives effect to intention of that Parliament, 'but it may only elicit that intention from the actual words of the statute.'<sup>165</sup>

In this Chapter it has been argued that the modern view about interpretation of the proviso to s 6 has been based on a misconception by the courts that the proviso is a separate clause, independent of the provision to which it is a proviso. It is concluded that the proviso has been interpreted grammatically, that is, taken in isolation, according to the rules of grammar - standing alone and without taking into consideration the context of the *Statute of Monopolies* and the main purpose of s 6. By treating the proviso independently, the proviso and, in particular, the term 'generally inconvenient' has lost its original meaning. The grammatical or literal interpretation leads the term being treated as a public policy clause relating to a restraint of trade and a separate requirement for patentability, capable of being used as a sole ground for denial of patent protection. It is argued in the Chapter that the drafters of s 6 did not intend the term be given this role.

From history of s 6 it follows that, notwithstanding the ambiguity of the term 'generally inconvenient', if one adopts the general rule of interpretation of provisos<sup>166</sup> and thus reads s 6 as a whole, it is clear that the intention of the founders was that if an invention otherwise satisfies the requirements of manner of manufacture, inventiveness, novelty and usefulness (located in the main provision

---

<sup>161</sup> Edward Coke, 4 *Institutes of the Laws of England* (1644), 330.

<sup>162</sup> Bennion, above n 127, 345.

<sup>163</sup> *R v Wimbledon JJ, ex p Derwent* [1953] 1 QB 380, 384.

<sup>164</sup> Bennion, above n 127, 3.

<sup>165</sup> Langan, above n 127, 1; see also Maxwell, above n 129, 1; Bennion, above n 127, 345-347.

<sup>166</sup> See Part 5.5.3 of this Chapter.

of the section), the invention should not be declared generally inconvenient on the basis that the monopoly simply restricts others from trade or its use. This view corresponds with the position of Heerey J in *Welcome Real-Time SA v Catuity Inc*,<sup>167</sup> who rejected a submission regarding general inconvenience on similar grounds.<sup>168</sup>

This submission should not be taken as implying that public policy should never be considered in deciding patentability of inventions. The argument is that public policy considerations should only be made where the legislature specifically directs them to be made and this should be done by bodies other than judiciary. This proposition is addressed in the next Chapter.

---

<sup>167</sup> [2001] FCA 445.

<sup>168</sup> It seems that Heerey J has changed his view in relation to the meaning of general inconvenience since *Bristol-Myers Squibb Co v F H Faulding & Co Ltd* [1998] 860 FCA 22. As discussed above, in this case His Honour held that patenting of methods of medical treatment was 'generally inconvenient'. See discussion of *BMS* in Chapter 4, Part 4.5.2.2.

## CHAPTER 6: CONCLUSIONS AND PROPOSALS

### 6.1 INTRODUCTION

The previous five Chapters of this thesis have provided an historical and contemporaneous analysis of patenting of methods of medical treatment of human beings in Australia and other common law countries that derived their origin from the UK law. It has also inquired into the history and concept of patent law and examined the rules of statutory interpretation as they relate to s 6 of the *Statute of Monopolies 1624* (the ***Statute of Monopolies***). In summary, this thesis has:

1. described the approaches adopted in a number of countries in dealing with patenting of methods of medical treatment of human beings;
2. explored the deficiencies (if any) with the approaches;
3. examined the justification for denying patents to methods of medical treatment inventions in countries outside Australia; and
4. critically analysed the advancement of the general inconvenience objection against such patents to import public policy considerations into Australian law.

In this Chapter, the key conclusions of this thesis will be summarised and a set of proposals will be made. The proposals in this Chapter aim to provide practical tools to assist the courts, Australian Patent Office or other relevant body in assessing inventions relating to methods of medical treatment of human beings.

### 6.2 THE EXCLUSION IN PRACTICE – CHAPTERS 1- 3

The analysis of patenting of methods of medical treatment of human beings in common law countries has revealed a consistent pattern of exclusion of methods of medical treatment from *C & W's Application*<sup>1</sup> in 1914 onwards. However, the rationale for the exclusion has changed over time in parallel with the changes to the interpretation of the manner of manufacture requirement.

---

<sup>1</sup> *In the Matter of C & W's Application for a Patent* (1914) 31 RPC 235.

Since the 1970s,<sup>2</sup> the exclusion of methods of medical treatment has largely been based on the public policy concern that patenting of methods of medical treatment may restrict physicians in practicing medicine. The argument that has been put in to the legislatures and the courts and in the associated academic commentary is that, in order to ensure the best possible health treatment, physicians must always be free in their choice of treatment. Based on this argument, the UK, other European countries, Israel, Canada and New Zealand (as well as countries in Asia, Africa, North America, South America, Central America) exclude methods of medical treatment from patent protection.

However, the exclusion of methods of medical treatment has not been always based on these public policy reasons. Since 1914, the courts appeared to be comfortable with the long established grounds for such exclusion, based on the decision of English court *C & W's Application* that such inventions lacked 'commercial value'.<sup>3</sup> However, the foundation for the exclusion pronounced in the case of *C & W's Application* was removed by subsequent decisions in *NRDC*<sup>4</sup>, *Swift*<sup>5</sup> and *Schering*.<sup>6</sup> These cases clearly show that methods of medical treatment can have commercial value, just as much as the drugs and devices used in medical treatment. However, since the exclusion of such methods had become established practice at that time, in the absence of any express exclusion in the legislation itself, the UK courts turned to the application of s 6 of the *Statute of Monopolies*, which declares a patent void if it is 'generally inconvenient' to the society. Accordingly, patents to methods of medical treatment were declared 'generally inconvenient' on the basis that such patents might restrict medical practitioners from using patented medical treatment inventions. Thus, the proviso to s 6 became a new ground on which to base the refusal to patents to methods of medical treatment in the UK.

This long history of the prohibition of methods of medical treatments in the UK, and also in other European countries, led to the enactment of s 4(2) of the *Patents Act 1977* (UK), Art 52(4) of the EPC and other relevant European provisions, which expressly exclude methods of medical treatment of the human or animal body by surgery or therapy and diagnostic methods practiced on the human or animal body from patentability by treating them as not 'susceptible of industrial application'. The interpretation of the wording of Art 52(4) 'shall not be regarded as' leads to the conclusion that such methods would in fact be

---

<sup>2</sup> *Eli Lilly & Company's Application* [1975] RPC 438.

<sup>3</sup> *In the Matter of C & W's Application for a Patent* (1914) 31 RPC 235.

<sup>4</sup> *National Research Development Corporation v Commissioner of Patents* [1959] 102 CLR 252.

<sup>5</sup> *Swift & Co v Commissioner of Patents* [1961] RPC 147.

<sup>6</sup> *Schering AG's Application* [1971] RPC 337.

susceptible of industrial application but for artificial prohibition created by Art 52(4).

Notwithstanding the prohibition on patents for methods of medical treatment created by Art 52(4), the legislation of member states of the EPC, and the legislation in Israel legislation and exclusion adopted by the Canadian and New Zealand courts, these jurisdictions have adopted special rules for allowing claims directed to the protection of the *first* and/or *second medical use* of a known products. These claims have been called 'Swiss-type claims'.

These patent applications to the first and/or second medical use of known products are usually directed to treatment of a particular disease and consist of instructions to the physician on how to employ a certain medical substance to treat the disease. The consequence of allowing these Swiss-type claims is that they provide an indirect way for applicants to obtain patent protection for therapeutic methods of medical treatment. With the introduction of the Swiss-type claims format, patent examiners are left with no capacity to exclude of methods of medical treatment involving first and second therapeutic applications, irrespective of whether or not their governing legislation or case law proscribes patenting of methods of medical treatment. Accordingly, only 'pure' methods of medical treatment, such as methods of treating human illness by surgery and/or diagnostic methods are left outside protection of the Swiss-type claim.

Additionally, in considering whether a patent request regarding a method of medical treatment is allowable under Art 52(4) EPC and associated legislation in member states, the critical questions remains whether it is going to be performed on a *living* body and whether this is a method for the treatment of the human or animal by therapy or surgery. This limitation has created some concern in relation to methods of diagnosis, because the law is not clear as to whether such methods are patentable in Europe<sup>7</sup> and Canada<sup>8</sup>.

It is suggested in this thesis that the technical criteria in Art 52(4) EPC should not be the only considerations with regard to patent applications for methods of medical treatment. Such patent applications should also be read in conjunction with the exclusionary provisions of Art 53 EPC, which provide that inventions the publication or exploitation of which would be contrary to '*ordre public*' or *morality*, must be prohibited. Equivalent provisions allowing the exclusions of inventions

---

<sup>7</sup> T 385/86, *Non-Invasive Measurement/Bruker*.

<sup>8</sup> *Merck & Co v Apotex* (1995) 59 CPR (3d) 133; *Re Application No. 016, 962*; *Re Application No. 880, 719* and *Re Application No. 372,233*.

from patenting on ethical or social policy grounds also exist in the legislation of EPC member states and in New Zealand legislation.<sup>9</sup> Arguably, these provisions derive from the necessity to protect social values and public interest that could be traced back to the early cases of the Tudor period, and the time surrounding the enactment of the *Statute of Monopolies 1624* discussed in Chapter 5.

It is submitted that if methods of medical treatment inventions are meant to be excluded from patentability by the EPC or its member states, they should be excluded as 'exceptions to patentability' under Art 53 EPC and its equivalents in the legislation of member states. This proposition corresponds with the opinion voiced in academic legal literature with regard to the provision in Art 52(4) EPC where the connection between the exclusion of methods of medical treatment with the requirement of industrial applicability was announced as being systematically inappropriate<sup>10</sup> and a legal fiction.<sup>11</sup>

Although the *Patents Act 1953* (NZ) does not expressly excludes patents to methods of medical treatment, New Zealand courts have taken an approach similar to that of Europe, finding that since methods of medical treatment have traditionally been excluded from patentability at common law, it is Parliament's responsibility to provide otherwise.<sup>12</sup> It has now been recognised that the statutory basis in New Zealand for the exclusion of methods of medical treatment is that of general inconvenience.<sup>13</sup> According to the New Zealand courts, this is a separate issue from whether or not an invention satisfies the 'manner of manufacture' requirement, although general inconvenience also finds its statutory basis in s 6 of the *Statute of Monopolies*. Despite this, the ability to use general inconvenience as a ground to exclude inventions from patentability is not well supported in New Zealand law. The exclusion from patentability of methods of medical treatment is based on policy grounds,<sup>14</sup> mainly that the use of such methods would be contrary to morality.<sup>15</sup>

A review of the background of US Public Law 104-208 reveals that substantial change in US patent law was provoked by a single patent lawsuit, *Pallin v*

---

<sup>9</sup> Section 1(3) of the *Patents Act 1977* (UK) and s 17 of the *Patents Act 1953* (NZ).

<sup>10</sup> Gall, 'Patentability in the Field of Pharmacy/Therapy' (1991) 10 *Management Intellectual Property*, 38.

<sup>11</sup> Rainer Moufang, 'Methods of Medical Treatment Under Patent Law' (1993) 24 *International Review of Industrial Property & Copyright Law*, 32.

<sup>12</sup> *Pharmaceutical Management Agency Ltd v Commissioner of Patents* [1999] NZCA 332; *Pfizer Inc v Commissioner of Patents* [2004] NZCA 104.

<sup>13</sup> *Pfizer Inc v Commissioner of Patents* [2004] NZCA 104, [26].

<sup>14</sup> *Pharmaceutical Management Agency Ltd v Commissioner of Patents* [1999] NZCA 332, [29].

<sup>15</sup> By virtue of s 17 of the *Patents Act 1953* (NZ).



*Singer*<sup>16</sup>. Even though infringement litigation is generally not rare in American society, it was certainly rare at the time in the world of surgeons and physicians. Doctors viewed this litigation as a threat to medical science, which might have devastating consequences. However, it is submitted that since medical method patents have been allowed in the US for nearly forty years,<sup>17</sup> it was already proven that such patents were not a threat to the promotion of medical welfare. Moreover, as infringement litigation was so uncommon among the medical profession, the legislative reaction (by enacting the Public Law 104-208<sup>18</sup>) on a single case, resulting in a substantial reduction in remedies available for methods of medical treatment patent infringement, was arguably premature and unwarranted.

Notwithstanding Public Law 104-208, the US law providing protection for 'uses of compositions'<sup>19</sup> clearly eliminates any need for Swiss-type claims. In this way methods of medical treatments can be indirectly enforced in the US. The experience of the US in granting patent protection for methods of medical treatment might be treated as a useful example to solve the issue of patentability of such methods around the world. Though there is no authority for such proposition, based on the reviewed case law and practices, it is the author's opinion that, the practice of allowing methods of medical treatment patents in the US may have been an inspiration for indirect protection of such methods in Europe, Canada, Israel and New Zealand through the vehicle of Swiss-type claims. It could also be suggested that the US approach towards patentability of all medical inventions inspired the judges of the Federal Court of Australia in *Anaesthetic Supplies Pty Ltd v Rescare Ltd*<sup>20</sup> and *Bristol-Myers Squibb Co v F H Faulding & Co Ltd*,<sup>21</sup> to rule that methods of medical treatments were patentable in Australia.

At the present time, Israeli legislation expressly prohibits patenting of methods of medical treatment.<sup>22</sup> However, the case of *The Wellcome Foundation Ltd v Plantex Ltd*<sup>23</sup> made a significant contribution in changing attitudes towards patentability of such methods in Australia, and still might play a valuable role in Israeli patent law in the future.

---

<sup>16</sup> 36 USPQ 2d (BNA) 1050 (D Vt 1995).

<sup>17</sup> *Ex Parte Scherer* 103 U.S.P.Q. 107 (Pat. Off. Bd. App. 1954).

<sup>18</sup> Amendment to 35 US Code § 287(c), known as Pubic Law 104-208.

<sup>19</sup> By virtue of § 616 (c)(2)(A) of Title 35 US Code § 287 (c).

<sup>20</sup> (1994) AIPC 91.

<sup>21</sup> [2000] FCA 316.

<sup>22</sup> See Section 7 of the *Patents Act* 1967 (Israel).

<sup>23</sup> [1974] RPC 514, published in Hebrew in PDI (Supreme Court Judgments), vol. 27, p 29.

Another landmark case which addressed the issue, was the decision reached by Davison CJ in the New Zealand case of *Wellcome Foundation Ltd v Commissioner of Patents*.<sup>24</sup> Though the Court of Appeal overturned Davison CJ's decision that methods of medical treatment were patentable subject matter, the case was instructive for Australian judges faced with the same task.

Although a detailed evaluation of the position in Europe is beyond the scope of this thesis, some suggestions are made below as to how member states of the EPC might better approach the issue of patenting of methods of medical treatment based on the analysis of the case law and legislative provisions presented in Chapters 1-3 and summarised above.

- 1 Since only 'pure' surgical, therapeutic and diagnostic methods are excluded from patent protection, as a matter of practice, it appears unlikely that a medical practitioner would make a patent claim for such method. Instead, a practitioner who wishes to patent a new medical procedure involving therapeutic substances in Europe would draft their claim in the Swiss-type format. Thus, since the Swiss-type format causes therapeutic methods of medical treatment to be de facto no longer excluded from patent protection, excluding such methods from patenting has little practical value. Rather than taking the root of creating a 'legal fiction' using the Swiss-type format, a more realistic approach should be taken by *allowing* patentability of method of medical treatment claims.
- 2 However, bearing in mind competing interests and public policy concerns regarding social impact of patents to methods of medical treatment inventions, patent examiners should seriously consider whether or not they should *be excluded on public policy grounds* on a case by case basis.
- 3 There is scope to consider such matters in European patent law in the form of the *ordre public* and morality exclusion under Art 53(a) of the EPC, though according to current interpretation of Art 53(a), the exclusion can be invoked only in extreme cases. As it was demonstrated in Chapter 5, the scope of any term in legislation (and the '*ordre public*' and 'morality' is not an exception) is a matter of interpretation, and in the absence of clear legislative definition of the term, it is usually left for the courts to interpret. Since application of the '*ordre public*' and morality exclusion involves 'a careful weighing up' of competing interest,<sup>25</sup> there is scope to argue that

---

<sup>24</sup> [1979] 2 NZLR 591.

<sup>25</sup> *Harvard/Oncomouse* [1990] EPOR 501, 513.

instead of express prohibition of patents to methods of medical treatment, each patent application must be examined in conjunction with the '*ordre public*' and morality considerations, and, by using the 'weighing up' exercise, considered in accordance with the circumstances of particular case. Only those methods that are likely to be against *ordre public* or morality should be refused patenting.

### 6.3 THE AUSTRALIAN POSITION – CHAPTER 4

Australian patent law, in contrast with more conservative jurisdictions in Europe, Canada, Israel and New Zealand, recognises that methods of treatment of the human body should be patentable in order to provide considerable incentive for medical research and development. However, opponents to the patentability of methods of medical treatment in Australia have attempted to rely on the judicial interpretation of s 6, arguing that granting a patent to such methods would be generally inconvenient within the meaning of s 18(1) of the *Patents Act* 1990 (Cth) (the **1990 Act**).<sup>26</sup>

The examination of s 18(1) in Chapter 4 of this thesis revealed that while the definition of a valid patent, from first sight, appears to be simple, identifying the boundaries of each requirement is a difficult task. Due to the overlapping concepts of 'patentable invention', 'invention', 'newness', 'novelty' and 'manner of new manufacture' the 1990 Act is far from being clear. Moreover, the definition of 'patentable invention' provides little or no guidance on whether methods of medical treatment of human beings could be patentable subject matter, or whether it could possibly be decided that patenting of such methods would or would not be 'generally inconvenient' under the proviso to s 6 of the *Statute of Monopolies*, which is a part of the definition of 'invention'. For these reasons it is concluded that the 1990 Act needs to be amended to provide a more succinct definition of a 'patentable invention'.

Based on judicial interpretation, and in the absence of any express guidance in the legislation itself, in Australia, methods of medical treatment are considered to be a 'manner of manufacture' within s 6 of the *Statute of Monopolies*.<sup>27</sup> This approach can be contrasted to the approach adopted by the EPC member states

---

<sup>26</sup> See, eg, *Anaesthetic Supplies Pty Ltd v Rescare Ltd* (1994) 50 FCR 41 (Sheppard J); *Bristol-Myers Squibb Co v F H Faulding & Co Ltd* [2000] FCA 316 (Heerey J); W. Yang 'Patent Policy and Medical Procedure Patents: The Case for Statutory Exclusion From Patentability' (1995) 1 *Boston University Journal of Science and Technology Law* 5; P. Loughlan 'Of Patents and Patients: New Monopolies in Medical Methods' (1995) 5 *Australian Intellectual Property Journal* 13.

<sup>27</sup> *National Research Development Corporation v Commissioner of Patents* [1959] 102 CLR 252, 271.

that expressly pronounce methods of medical treatment as '[un]susceptible of industrial application'.<sup>28</sup> Yet, it is still arguable whether or not such methods are patentable in Australia due to the 'generally inconvenient' exclusion in the proviso to s 6 of the *Statute of Monopolies* or through any other means. In similarity with the reasoning used to justify the exclusion in UK case law in the 1970s,<sup>29</sup> it has been argued in Australia that the main obstacle to patenting of methods of medical treatment inventions is the general inconvenience exclusion on the basis that it allows for the introduction of public policy considerations.<sup>30</sup>

Nevertheless, following *Rescare*<sup>31</sup> and *BMS*<sup>32</sup> methods of medical treatment have been granted patent protection in Australia. Consequently, compared to the European countries, Canada, Israel and New Zealand, there is no need to use an indirect way to get patent protection for a method of medical treatment through the vehicle of the Swiss-type format.

Patentability of such methods in Australia, therefore, provides a clear solution to the existing problem in practical terms. From a practical point of view, it is not difficult to establish the validity and define the precise scope of a claim to a method of medical treatment, compared to the Swiss-type form. The nature of the act of infringement is also certain here, and thus making a clearer case for an infringement action. The Swiss-type claim, on the other hand, creates uncertainty as to whether the claim is for the *manufacture* of the medicament, its *use*, or *manufacture with a view to use*.<sup>33</sup> Moreover, patents for medical treatment methods, unlike the Swiss-type patents, also assist potential infringers in determining what they are and are not entitled to do without risking an infringement action being brought against them.<sup>34</sup>

*Rescare* and *BMS* seem to have shut the door somewhat on the advancement of the general inconvenience argument against patenting of methods of medical treatment. However, the true ambit of general inconvenience remains uncertain and it is possible that attempts could be made to introduce public policy considerations under its veil. Chapter 4 illustrated that the Full Court of the

<sup>28</sup> Section 4(2) of the *Patents Act 1977* (UK) and Art 52(4) of the EPC.

<sup>29</sup> *Eli Lilly & Company's Application* [1975] RPC 438; *Upjohn Company (Robert's) Application* [1977] RPC 94.

<sup>30</sup> *Joos v Commissioner of Patents* (1972) 126 CLR 611; *Anaesthetic Supplies Pty Ltd v Rescare Ltd* (1994) 50 FCR 41; *Bristol-Myers Squibb Co v F H Faulding & Co Ltd* [2000] FCA 316.

<sup>31</sup> *Anaesthetic Supplies Pty Ltd v Rescare Ltd* (1994) 50 FCR 1.

<sup>32</sup> *Bristol-Myers Squibb Co v F H Faulding & Co Ltd* [2000] FCA 316.

<sup>33</sup> J Savina, 'The Patentability of the Second Therapeutic Application – Why must the Law be Changed?' (1995) 8 *Patent World* 32, 34.

<sup>34</sup> *Bristol-Myers Squibb Co v Baker Norton Pharmaceuticals Inc* [1999] RPC 253, 272 (Jacob J).

Federal Court of Australia was not willing to use general inconvenience to justify exclusion of methods of medical treatment in the case of *BMS*. This thesis does not question whether the decision in that case was correct, but questions the reasoning behind the application of general inconvenience. The court in *BMS* accepted that the general inconvenience proviso could be used to introduce public policy considerations in patent examinations in Australia. For this reason Chapter 5 analysed the origins and history of patent law to ascertain whether there is any basis for using general inconvenience to import such public policy considerations into Australian law.

#### 6.4 THE PROVISO TO SECTION 6: ITS ORIGINAL MEANING

This thesis has revealed that there remains great deficiency of case law on the meaning of the proviso,<sup>35</sup> and in particular, the meaning of 'generally inconvenient'. Until today, neither the case law nor legislation has furnished an entirely clear answer as to the circumstances in which a monopoly would be generally inconvenient. In the absence of the case law on the construction of the term in question, it was felt necessary in this thesis to examine the pre-enacting and enacting history of the *Statute of Monopolies* to ascertain the scope of the proviso to s 6. In order to determine, the reasons for enacting the *Statute of Monopolies* and its proviso it was necessary to examine the mischief for which the common law did not provide.

These analyses led to the main conclusion of Chapter 5, that s 6 of the *Statute of Monopolies* was aiming to spell out that in order to be patentable a commodity must satisfy requirements of novelty, manner of manufacture, no prior use in the realm and usefulness. By using words 'so as also they' at the end of the main provision, s 6 was making a clarification by means of the proviso, aiming to transmit a message that if an alleged new commodity lacked the abovementioned requirements, it must not be granted a patent. Since the whole idea of s 6 was *granting monopolies to something new and useful*, giving the grant of letters patent to something lacking novelty or utility would prevent a craftsman from carrying on his ordinary trade, *thus be inconvenient* for that craftsman and the society as a whole. According to this interpretation, the proviso therefore is just an explanation of the logical consequence of granting a monopoly to a previously known or useless trade or industry.<sup>36</sup>

---

<sup>35</sup> See R Frost, *Treatise on Letters Patent for Inventions* (1912), 30-31.

<sup>36</sup> The historical evidence revealed that 'inconvenient', 'contrary to law', or 'mischievous to the state', had no distinction in their meaning, thus the above interpretation is relevant to the whole proviso.

The history of *Statute of Monopolies* indicates that notwithstanding the term was used to advance public policy reasons, the basis for those policy reasons was different from those advanced by modern courts. Even though the policy reasons perhaps use similar weighing technique and arrive at a similar conclusion (invalidation of patents on public policy grounds), they are of different nature or based on different concept. In the early days the discretion was exercised in the name of the public good to prevent *unlawful* inventions that failed to satisfy requirements of *invention and novelty*. Due to their unlawful nature such inventions were considered to be inconvenient to the Commonwealth.

The modern courts, on the other hand, advance the 'generally inconvenient' objection against method of medical treatment inventions, relying on the *restraint of trade* argument and/or an assumption that even though a method of medical treatment might be inventive, new and useful, it would nevertheless restrict medical practice, and thus void. In deciding the meaning of the general inconvenience, the modern courts did not examine the history of s 6 and the original purpose of the proviso. Rather, they interpreted the proviso grammatically or literally by employing moral and public policy judgments.

#### **6.4.1 Where does the term 'generally inconvenient' fit in?**

Applying the legislative intention regarding the term 'generally inconvenient' within the context of current common law and s 18 of the *1990 Act*, it is concluded that the term fits in between the concept of 'manner of new manufacture', redefined by the High Court of Australia in *NRDC*<sup>37</sup> and the term 'useful' in section 18(1)(c). Accordingly, the concept of general inconvenience involves the three requirements: the invention must be new, inventive (not obvious), and useful.

It is submitted that the term 'generally inconvenient' in the proviso of s 6 no longer has a role to play in modern Australian patent law. In 1624 it may be that it was necessary to include this term to emphasise the importance of having a lawful invention, but this is no longer the case. The *1990 Act* clearly spells out that patents can only be granted for inventions that are new, inventive and useful. This was not the case in the *Statute of Monopolies*, hence the need for the general inconvenience proviso. Given that the three requirements of novelty, inventiveness (not obvious), and usefulness are now expressly listed as requirements for valid patents, continued use of the term general inconvenience

---

<sup>37</sup> *National Research Development Corporation v Commissioner of Patents* (1959) 102 CLR 252, 269.

and indeed the proviso as a whole does not have any significance or carries little weight. As such, there is no justification for continued reference to these provisions in Australian patent legislation and the most desirable outcome would be for the *Patents Act 1990* to be amended to delete all reference to the proviso.

## 6.5 WHAT NEXT?

In the meantime, in the absence of a clear definition of the terms 'patentable invention' and 'generally inconvenient' and clear High Court authority on the question of whether methods of medical treatment patenting is 'generally inconvenient', the Australian Patent Office must be guided by the Full Federal Court decisions in *Rescare* and *BMS*. In those cases, although the judges decided it was appropriate to consider public policy arguments under the guise of general inconvenience, public policy was nevertheless deemed insufficient to justify exclusion of patents for methods of medical treatment. Currently, by adopting these decisions, the Patent Office declares:

[i]t is now *firmly established* that methods of medical treatment are patentable subject matter, and *there is no objection to this aspect* of an invention.<sup>38</sup>

However, such definite interpretation of the case law by the Patent Office might be undermined in future. The point is that *Rescare* and *BMS* do not close the debate about whether methods of medical treatment should be patentable and the decision is yet to be made.

## 6.6 DEFICIENCIES IN REVIEWED APPROACHES

The approaches analysed in Chapters 1-4 in respect of patentability of methods of medical treatment of human beings indicate that *all approaches have their own problems*. These are summarised below.

1. The express exclusions in Europe and Israel can be worked around by skilled patent attorneys in drafting a patent application in the form of the Swiss type claims, thus making the exclusions of minimal value.
2. The same could be said about prohibition of methods of medical treatment by Canadian and New Zealand courts, which treat such methods as inherently unpatentable in Canada, and rely on

---

<sup>38</sup> APO. Manual of Practice and Procedure-National, June 2001, at para8.2.13.3 (*Emphasis added*)

longstanding practice of exclusion in New Zealand (including the general inconvenient argument). The prohibition can also be avoided via vehicle of the Swiss type claims in these jurisdictions.

3. The justification for exclusion based on general inconvenience in New Zealand and arguments to this effect advanced in Australia have no merit either. This is because it is questionable whether the term 'generally inconvenient' includes public policy considerations in its scope, and whether the interpretation of the term adopted by the courts has a sound historical basis.
4. The US exemption approach dictated by the provisions in the Public Law 104-208 is also problematic, as, on one hand, it allows patents to methods of medical treatment, but at the same time, takes away their value by making them unenforceable against medical practitioners and related health care entities.

Based on the above conclusions the author makes the following proposals, which may be taken into account under existing Australian patent law by patent examiners and courts in addressing patenting of methods of medical treatments of human beings.

## **6.7 PROPOSALS**

### **6.7.1 Option One**

In the case that s 18 of the 1990 Act remains unaltered, this option proposes that in interpreting ambiguous terms such as 'generally inconvenient', the courts should search for and follow the intention of the makers of the legislation and not the judge's preferred meaning or that of today's circumstances. As such, if the Australian courts are presented with another opportunity for considering the patentability of methods of medical treatment, or indeed the patentability of any other subject matter that might raise public policy concerns, they should not be guided by the conclusions of the courts in *Rescare* and *BMs* with regard to the ambit of general inconvenience. Since the court decisions in *Rescare* and *BMS* did not truly reflect the legislative intention of the drafters of the provision, later courts might be pointed to this defect in interpretation and distinguish these decisions. This is not to say that the ultimate decisions in *Rescare* and *BMS* should not be followed. It is the interpretation of general inconvenience propounded by the courts in those decisions that raises concerns.



### 6.7.2 Option Two

Another approach would be to amend the 1990 Act by adding to the current definition of 'patentable invention' a specific legal definition of the term 'generally inconvenient'. This would provide a more succinct definition of a 'patentable invention' and clear up the uncertainty in Australian patent law in relation to interpretation of the proviso to s 6 of the *Statute of Monopolies*.

As noted in Chapter 5,<sup>39</sup> it is proposed that the proviso to s 6 should be treated as a provision that is dependent on the main statement. Section s 6 therefore may state the following:

- (1) Provided also that any declaration before mentioned [*monopolies*] shall not extend to any letters patent and grants of privilege for the term of fourteen years or under, thereafter to be made, of the sole working or making of any manner of new manufactures within this Realm, to the true and first inventor and inventors of such manufactures which others at the time of making such letters patent and grants shall not use.
- (2) *Those monopolies that lack of any requirement provided in subsection (1) above shall be held contrary to the law or mischievous to the state, by raising prices of commodities at home, or hurt of trade, or generally inconvenient.*

### 6.7.3 Option Three

Taking into account that:

- (a) there is no modern case law regarding interpretation of the term 'generally inconvenient' and the term is ambiguous;
- (b) arguably, the concept of general inconvenience has already been covered by the requirements of novelty, inventiveness and usefulness – the existing requirements of s 18 of the 1990 Act; and

---

<sup>39</sup> Part 5.5.3.

- (c) the fact that Australia has entered into the *Agreement on Trade-related Aspects of Intellectual Property Rights 1995 (TRIPS)*<sup>40</sup> and *Free Trade Agreements*,<sup>41</sup> neither of which refers to general inconvenience,<sup>42</sup>

it is concluded that term 'generally inconvenient' adds nothing to the criteria of patenting and the whole proviso has not value.

For these reasons, an alternative proposal would be to alter the current definition of 'patentable invention' by:

1. striking out the phrase 'within the meaning of Section 6 of the Statute of Monopolies' and adding to s 18 a provision which would allow inventions to be excluded from patentability where it is necessary to prevent their commercial exploitation in order 'to protect *ordre public* or morality, including protection of human, animal or plant life or health',<sup>43</sup> and
2. additionally including a specific legal definition of the terms '*ordre public*' and 'morality'.

Adopting this option would mean altering the current definition of 'patentable invention' by departing from the use of the proviso to the *Statute of Monopolies*. This would have advantage of defining more clearly the requirements for a patentable invention. However, if the reference to the proviso to s 6 of the *Statute of Monopolies* is removed from the 1990 Act, there will be no authority for the Commissioner of Patents or the courts to refuse patents where the use of an invention would raise social and ethical concerns.<sup>44</sup> In addressing this issue it is proposed to introduce the public policy ground for objection as a separate criterion for the patentability, which does not form part of the 'manner of new manufacture' test. It is argued that this criterion should be a distinct requirement

<sup>40</sup> See, eg, Article 27.2 of *Agreement on Trade-Related Aspects of Intellectual Property Rights Including Trade in Counterfeit Goods* (1994) 25 IIC 209 (TRIPS).

<sup>41</sup> *North American Free Trade Agreement* (17 December 1992, Ottawa) (NAFTA); *Australian-US Free Trade Agreement*, [2005] ATS 1.

<sup>42</sup> Though those Agreements refer to '*ordre public*' and 'morality'. Trade agreements such as NAFTA and TRIPS allow member states to exclude methods of medical treatment from patent protection. In article 1709(3)(a) of NAFTA, for example, parties are permitted to exclude from patent protection 'diagnostic, therapeutic and surgical methods for the treatment of humans or animals.' Similarly, Art 27.2 of the TRIPS agreement permits member states to exclude from patent protection 'diagnostic, therapeutic and surgical methods for the treatment of humans and animals.'

<sup>43</sup> See Article 27.2 of the TRIPS Agreement.

<sup>44</sup> Apart from s 50(1)(a) of the 1990 Act that allows the Commissioner of Patent to refuse patents that are contrary to law.

for patenting, along with a manner of manufacture, novelty, inventive step, obviousness and usefulness.

Thus, similar to the proposition made in relation to the European patent law practice, adopting this option would allow examination of each patent application for a method of medical treatment in conjunction with the '*ordre public*' and morality exclusion. Instead of an express prohibition of patents for all methods of medical treatment, an individual case by case approach of 'weighing up' public policy considerations would be involved. Only those methods that are likely to be against *ordre public* or morality should be refused patenting.

This amendment would harmonise the Australian requirements for patenting with that used in other countries. However, this would not necessarily lead to the conclusion that patentability of methods of medical treatment should be prohibited, as in Europe, Israel, Canada and New Zealand. To eliminate confusion as to the meaning of the terms '*ordre public*' and 'morality', a specific legal definition of these terms should be included in the 1990 Act. The definition adopted by the EPC and European Biotech Directive could provide some useful guidance in this respect. While Art 6 of the Biotech Directive only provides examples of the types of biotech-related subject matter that may be considered as contrary to *ordre public* or morality, it also provides guidance as to how to similar sets of examples might be formulated in other areas, including the area of methods of medical treatment.

#### **6.7.4 Option Four**

This option is focused on non-involvement of courts in considering public policy issues. It suggests that, while allowing methods of medical treatment to be patented, precautions should be taken in eliminating involvement of the courts in deciding public policy matters, by giving this task to an independent advisory and policy making body. This option proposes an involvement of an agency for making public policy decisions. The Agency should be either a part of the Australian Government, a politically accountable institution to which the Government would delegate a power for policy-related decisions regarding patentability, or an independent body.

One example of a suitable agency might be an Ethics Board to, which Australian Patent Office (**APO**) can refer all applications that raise public policy issues. Once an inventor makes a patent application to the APO, the APO would assess an alleged invention to determine whether it satisfies all the requirements of

patentability under s 18 of the 1990 Act, and, if necessary, refer it to the Ethics Board for public policy assessment. The Ethics Board then would make policy choices and resolve competing views as to whether the alleged invention is either 'generally inconvenient' (in the case if the 1990 Act remains unaltered), or against '*ordre public*' and 'morality' (in the case if the 1990 Act includes provision containing these terms and does not provide their legal definition).

In deciding whether a particular invention should be given patent protection, the Ethics Board should consider issues such as protection of the public health, promotion of competition, dissemination of medical information, protection of patients and support of medical practitioners, while recognizing the effort made by an inventor and respecting their rights to obtain a reward for contributions made to the mankind.

The establishment and operation of such an agency is already a valid practice in the field of the tax law, where the Australian Tax Office is granted a policy-making responsibilities and power to exercise the Commissioner's of Taxation discretion in dealing with certain tax matters. In exercising the discretion, the Commissioner of Taxation is guided by administrative law principles that provide that each decision must be made according to the merits of each case, taking into account the purpose and policy of the *Income Tax Assessment Act 1997*.<sup>45</sup> A taxpayer who is not satisfied with the legitimacy of the discretion can approach a tribunal or court to consider whether, in the process of exercising the discretion, the Commissioner either abused his power, denied the taxpayer of procedural fairness or erred in law in interpreting the tax legislation.

It is proposed that the Australian Government should reconsider the scope of the APO's practice and instruct APO to seek approvals from the Ethics Board, when public policy issues are likely to arise. Similar to the practice of the Australian Tax Office, the Ethics Board might be given policy-making responsibilities (for example, the issuance of guidelines as to the scope of the public policy exclusion from patenting) as well as the power to exercise discretion under administrative law principles as to whether an alleged invention should be granted patent protection. A patentee who is not satisfied with the legitimacy of the discretion may appeal the decision of the Ethics Board to the court. However, the court would not consider issues of public policy, but only the legitimacy of the discretion exercised by the Ethics Board.

---

<sup>45</sup> The Taxation Ruling TR 98/12, paragraphs 17-20, 82, 87 and 91-93.

The above approach would force a reconsideration of the allocation of institutional authority between two institutional bodies – the legislature and judiciary. This would make a balance between judicial and administrative functions. Accordingly, when an issue becomes more political, it would be decided by politically responsible institution – the agency of the Government rather than the courts.

### **6.7.5 Option Five**

Adopting the US approach in dealing with methods of medical treatment inventions, and bearing in mind that there should be freedom in the medical practitioner's choice of treatment, this proposal would allow medical treatment patents to be granted, but would require from the patent holder a disclaimer of any right to sue medical practitioners utilizing the patented invention for medical or surgical purposes.<sup>46</sup> Alternatively, a new provision might be included in the 1990 Act, which would expressly exempt medical practitioners from liability for infringing a patent on a medical or surgical procedure in certain circumstances.<sup>47</sup>

However, as stated above, this approach would significantly devalue a patent given to the patent holder and thus, has the capacity to considerably discourage the incentive for medical research and development.

---

<sup>46</sup>Perhaps the US Public Law 104-208, discussed in Chapter 3 could be used as guidance for such disclaimer.

<sup>47</sup> Similarly, the US Public Law 104-208 might be considered here.

## BIBLIOGRAPHY

### BOOKS

- Aldous G, *Terrell on the Law of Patents* (11<sup>th</sup> ed, 1965)
- Bacon MA, *New Abridgement of the law*, (7<sup>th</sup> ed, 1832 ) vol VI
- Baker JH, *The Legal Profession and the Common Law* (1986)
- Baxter JW, *World Patent Law and Practice* (1968)
- Bennion F, *Statutory Interpretation, A Code* (2<sup>nd</sup> ed, 1992)
- Bernard & Kraber, *Lehrbuch des Patentrechts*, (4<sup>th</sup> ed, Munich, 1986)
- Coke E, *2 Institutes of the Laws of England* (1644)
- Coke E, *3 Institutes of the Laws of England* (1644)
- Coke E, *4 Institutes of the Laws of England* (1644)
- Cass F, *Legal History* (1998) vol 19
- Calvert R, *The Encyclopedia of Patent Practice and Invention Management* (1964)
- England S (ed), *Essays in Honour of Wallace Notestein* (1960)
- Fox HG, *Monopolies and Patents: A Study of the History and Future of the Patent Monopoly* (1947)
- Frost R, *Treatise on Letters Patent for Inventions* (1912)
- Hatsell, *Parliamentary Precedents* (1575)
- Hindmarch WM, *A Treatise on the law relating to patent privileges for the sole use of inventions* (1846)
- Hindmarch WM, *Treatise Relating to the Law of Patent Privileges for the Sole Use of Inventions* (1847)
- Holdsworth WA, *History of English Law* (3<sup>rd</sup> ed, 1945) vol 4
- Langan P, *Maxwell on the Interpretation of Statutes* (12<sup>th</sup> ed, 1969, reprinted 2003)
- MacLeod C, *Inventing the Industrial Revolution: The English Patent System 1660-1800* (1988)
- Maitland, *The Constitutional History of England* (1950)
- Maxwell PP, *On the Interpretation of Statutes* (1875)

Pearce DC and Geddes RS, *Statutory Interpretation in Australia* (6<sup>th</sup> ed, 2006)

Price W Hyde, *The English Patents of Monopoly* (1913), vol 1

Ricketson S, *The Law of Intellectual Property* (1984)

*The Oxford English Dictionary*, (Clarendon Press, Oxford, 1970)

Thompson, *Magna Carta – Its Role in the Making of the English Constitution –1300-1629* (1943)

Van Caenegem W, *Intellectual Property Law and Innovation* (2007)

Viner C, *A General Abridgment of Law and Equity* (2nd ed, 1793)

## ARTICLES

Anderson S, 'A Right Without a Remedy: The Unenforceable Medical Procedure Patent' (1999) 3 *Marquette Intellectual Property Law Review* 117

Arthur G, 'Swiss Type Claims Held Valid in New Zealand' (2000) 20(8) *European Intellectual Property Review*, 380

Baker JH, 'Coke's Notebooks and the Sources of His Reports' (1972) 30 *Cambridge Law Journal* 59

Beier FK, 'Future Problems of Patent Law' (1972) 3 *International Review of Industrial Property & Copyright Law* 423

Brennan D and Christie A, 'Patent Claims for Analogous Use and the Threshold Requirement of Inventiveness' (1997) 25 *Federal Law Review* 237

Corre JJ, 'The Argument, Decision and Reports of *Darcy v. Allen*' (1996) 45 *Emory Law Journal* 1261

Culbert P, 'Patent Law Reform in New Zealand: Should Methods of Medical Treatment be Patentable?' (1997) *Patent World* 32

Davies D S, 'Further Light on the Case of Monopolies' (1932) 48 *Law Quarterly Review* 394

Davies D S, 'The Early History of the Patent Specification' (1934) 50 *Law Quarterly Review* 86

Duigan M and Dowling M, 'Threshold Test of Manner of Manufacture in Australia-What Next?' (1998) *Patent World*, September, 26

Gall, 'Patentability in the Field of Pharmacy/Therapy' (1991) 10 *Managing Intellectual Property*, 38

- Garland B, 'Methods of Medical Treatment Revised' (1997) 8 *Patent World* 1
- Garris JJ, 'The Case for Patenting Medical Procedures' (1996) *American Journal of Law and Medicine* 85
- Garvey M, 'New Medical-Procedure Patents Can't Be Infringed' (1996) *The IP Strategist* 5
- Gocyk-Farber B, 'Patenting Medical Procedures: A Search for a Compromise Between Ethics and Economics' (1997) *Cardozo Law Review* 1527
- Hawkins M, 'Swiss' Type Patent Claims on Hold' (1997) 9 *Patent World* 8
- Hulme EW 'The History of the Patent System Under the Prerogative and at Common Law' (1896) 12 *Law Quarterly Review* 141
- Hulme EW 'On the Consideration of the Patent Grant Past and Present' (1897) 13 *Law Quarterly Review* 313
- Hulme EW 'The History of the Patent System Under the Prerogative and at Common Law' (1900) 16 *Law Quarterly Review* 44
- Hurst D J, 'The problem of the Elderly Statute' (1983) *Legal Studies* 21
- Judge L, 'Issues Surrounding the Patenting of Medical Procedures' (1997) 13 *Computer & High Technology Law Journal* 181
- Kell D, 'Comments: Expanding the Frontier of Patentability: Methods of Medical Treatment of the Human Body' (1995) 4 *European Intellectual Property Review* 202
- Lancon P, 'Patentability in the Field of Therapy and Diagnosis' (1991) 22 *International Review of Industrial Property & Copyright Law* 893
- Loughlan P, 'Of Patents and Patients: New Monopolies in Medical Methods' (1995) 5 *Australian Intellectual Property Journal* 13
- Martin T, 'Patentability of Methods of Medical Treatment: A Comparative Study' (2000) 82 *Journal Of The Patent And Trademark Office Society* 381
- Meier B, 'The New Patent Infringement Liability Exception For Medical Procedures' (1997) 23, *Journal of Legislation* 265
- Moufang R, 'Methods of Medical Treatment Under Patent Law' (1993) 24 *International Review of Industrial Property & Copyright Law* 18
- Nichols S, 'Comment: Hippocrates, The Patent-Holder: The Unenforceability Of Medical Procedure Patents' (1997) 5 *George Mason Law Review* 227
- Noonan W, 'Patenting Medical Technology' (1990) 11 *The Journal of Legal Medicine* 263



Noonan W, 'Patenting Medical Surgical Procedures' (1995) 77 *Journal of the Patent and Trademark Office Society* 651

Padbury M, 'Inventiveness apart from Novelty and Inventive Step-The High Court's Decisions on Manner of Manufacture in Philips and Ramset' (1998) November, *Australian Intellectual Property Journal* 161

Panchen KE, 'Patentability in the Field of Therapy and Diagnosis' (1991) 22 *International Review of Industrial Property & Copyright Law* 879

Pila J, 'Methods of Medical Treatment Within Australian and United Kingdom Patents Law' (2001) *University of New South Wales Law Journal* 30

Reisman J, 'Physicians and Surgeons as Inventors: Reconciling Medical Process Patents and Medical Ethics' (1995) 10 *High Technology Law Journal* 355

Ring M, 'The Rubber Denture Murder Case: The True Story of the Vulcanite Litigations' (1984) 32 *Bull of the History of Dentistry* 1

Savina J, 'The Patentability of the Second Therapeutic Application – Why must the Law by Changed?' (1995) 8 *Patent World* 32

Speagle D and Dowling M, 'The 1990 Patents Act: Unfinished Reform' (1993) *Australian Intellectual Property Journal* 166

Sydall T, 'Method of Treatment Claims and Patent Law Reform in New Zealand' (1996) *The Chartered Institute of Patent Attorneys Journal* 423

Van Caenegem W, 'Technicality Requirement, Patent Scope and Patentable Subject Matter in Australia' (2002) 13 *Australian Intellectual Property Journal* 41

Van Caenegem W, 'The Technicality Requirement, Patent Scope and Patentable Subject Matter in Australia' (2002) 13 *Australian Intellectual Property Journal* 309

Walterscheid EC, 'The Early Evolution of the United States Patent Law: Antecedents' (4 parts) (1994) 76 *Journal of the Patent Office Society* 697, 849 (parts 1-2); (1995) 77 *Journal of the Patent Office Society* 771 (part 3); (1996) 78 *Journal of the Patent Office Society* 71 (part 4)

White AW, 'Patentability of Medical Treatment – Wellcome Foundation's (Hitching's) Application' (1980) 2 *European Intellectual Property Review* 364

White AW, 'Patentability of Medical Treatment Claims – The Nimodipin Cases' (1984) *European Intellectual Property Review* 38

Yang W, 'Patent Policy and Medical Procedure Patents: The Case for Statutory Exclusion From Patentability' (1995) 1 *Boston University Journal of Science and Technology Law* 5

## NEWSPAPERS

Sabra C, 'Why Is This Surgeon Suing? Doctors Split Over Patenting of Their Techniques' (1995) *New York Times*, June 8

## INTERNET

Canadian Patent Office, *Manual of Patent Office Practice* (1998), Government of Canada, Ottawa, see <http://patents1.ic.gc.ca/> (date accessed: 15 August 2007)

Deeth Williams Wall LLP - Patent and Trade Mark Agents: [www.dww.com](http://www.dww.com) (date accessed: 25 June 2007)

International Association for the Protection of Intellectual Property <http://www.aippi.org> (date accessed: 20 September 2007)

IPONZ Practice Note, October 1998: <http://www.iponz.govt.nz/pls/web/dbssiten.main>, (date accessed: 15 October 2007)